Globalization and ideology: ethics committees and global clinical trials in South Africa and Brazil

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Abstract

This study aims to explore the ideological implications of globalization, asking whether the global diffusion of guidelines and economic schemes leads to a parallel diffusion of interpretations, hopes and ideologies. I focus on the globalization of clinical trials sponsored by pharmaceutical companies to assess the efficacy and safety of new therapeutic compounds. I analyze the ways in which this globalization has been framed by the members of ethics committees, which are bodies responsible for assessing clinical research proposals submitted by both multinational companies and local researchers. I focus on the situations of South Africa and Brazil, two countries that have witnessed an important expansion in the number of global clinical studies conducted in their territories.

My theoretical framework is the theory of communicative action proposed by German sociologist Jürgen Habermas. According to this theory, social actors can be either self-oriented and frame the social context as an instrument (*instrumental rationality*), or take other actors into account and search for intercomprehension (*communicational rationality*).

Even though the presence of these two *rationalities* was detected in my study, it was seen that rationalities are composed by sub-groups, specks of *rationalities,* which I propose to name *mentalities.* The description and interpretation of the seven *mentalities* identified in my study (*pragmatic, bioethical, technical, healing, communitarian, analytical* and *critical*) is the main task undertaken in this thesis.

Interpreting *mentalities* is important to understand the political debates taking place in South Africa and Brazil (and, potentially, other countries). To engage in debates, social actors frequently mobilize claims and ideas gleaned from different *mentalities.* Over the last decades, the bioethical, technical and healing mentalities have acquired an important force and legitimacy. However, discordant discourses continue to be voiced, drawing on the ideological tools provided by the analytical and critical mentalities. Thus, ethics committees can be seen as a political arena, reproducing broad social debates.

Table of contents

Map

Index of tables

Index of figures

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Chapter 1 – Introduction

Globalization has reached a stage of high development, triggering processes whose consequences go beyond economic issues. Nowadays, it is possible to witness the formation of huge multinational corporations, the emergence of institutions endowed with international duties, the establishment of academic and scientific partnerships involving several countries, the intense circulation of products and people crossing over national frontiers, among other phenomena. It is then necessary to undergo important economic, infra-structural and institutional changes in many countries. By comparing the current historical situation with that which prevailed at the beginning of the twentieth century, it is possible to conclude that nowadays, people communicate, travel, buy and sell, research, learn and teach, in new ways. It is therefore important to ask if such changes have been accompanied by ideological shifts. In other words, the question arises whether new, globalized forms of communication, economic relations and academic studies can somehow lead to the emergence of new forms of thinking.

In my study I propose that, in an advanced phase of globalization, certain social processes and relations are also globalized, favouring the internationalization of some ideas, hopes and claims. These ideological patterns become socially available, that is, they can be recognized, consented to, and finally voiced by different individuals when they are asked to identify relevant issues and express their views. Thus, economic and technical globalization has provoked the parallel globalization of some *rationalities* and *mentalities,* which can be marshalled and diffused in different national and regional contexts.

The topic, although framed here from the viewpoint of sociological and cultural studies, has important linkages to economic, political and geographical approaches. In order to look at it with the particular tools of sociology and anthropology, but without refusing a fruitful dialogue with other disciplines, it is important to frame the questions to be explored accurately. Understanding the nature of globalization, as well as its

relations to the ideological domain, is therefore the first task to be accomplished here. The next section aims to realize this initial definition and exploration.

1.1. GLOBALIZATION AND IDEOLOGY

Relations between economic structures and ideologies constitute a classic topic in sociological and anthropological studies. In this section I refer to some analysts who are commonly mentioned when one deals with this issue. In a sense, one could say that the topic is already present in Saint-Simon's (1821/1925, 1803/1925) writings, in which the French thinker looked for an economic system which could derive from, as well as lead to, views of the world that oppose the dominant capitalist model.

Marx also strived to build up an interpretation to counter the dominant capitalistic ideology. Looking for a scientific interpretation, Marx proposed an analysis based on the idea of class structure. According to him, each social class, by engaging in market relations, would eventually develop its own class consciousness. In this way, the role played in the economic system would imply not only certain social relations but also the formulation of certain aspirations and worldviews. In the Marxian interpretation, capitalism would be underpinned not only by productive activities and unequal exchanges in the market, but also by sets of ideas springing from this economic structure. Hence, the famous Marxian concept of fetishism of commodities, according to which material products can assume a decisive position in the capitalist economy because, on the one hand, they hold human labour, whereas, on the other hand, they are thought to be endowed with a natural, intrinsic value (Marx, 1867/1990).

The tradition founded by Marx was explored by subsequent thinkers for whom ideology, consciousness and fetishism were paramount concepts. I am referring to analysts such as Gramsci (1948/2005), Marcuse (1964/1991), Habermas (1973), Poulantzas (1974), Olin Wright (1984/1989) and Lojkine (1981).

Simmel's (1903/1950) equally classic interpretation deals with the ideological stances triggered by modern society, and especially urban life. Analyzing the emergence and consolidation of a monetary economy, Simmel (1900/1997) concluded

that money is a social mediator entailing impersonal relations and asking for practical, objective calculations.

Rationalization was also a key topic in Weber's interpretation. Focusing on social action, taken as the basic unit of analysis, Weber explored the process through which society becomes more and more rationalized. Therefore, capitalism would be the economic manifestation of rationalizing trends that can also be verified in administration (bureaucracy), production (technology), knowledge (scientific exploration), music (graphic notations), among other fields. Therefore, modern society would be characterized by a specific mindset and ways of organizing objects and relations (Weber, 1979). In Weber's interpretation, primacy is given neither to ideologies nor social relations. This is why he could identify a strong reciprocity between the capitalist system and the protestant ethic (Weber, 1930/2001).

Weber's theoretical project was taken over by subsequent sociologists. Bourdieu (1989) proposed the famous concept of "cultural capital," stating that social opportunities have to do with the possession of money (economic capital) but also with access to some cognitive skills, frequently acquired through education. Breen's (2002) work is another example, in which Weber's ideas are associated with a class analysis.

Therefore, the history of sociological thought is full of examples in which analysts have shown interest in relationships between economic structures and ideologies. In anthropology, this interest is not less pronounced. Already in the first classic anthropological studies, carried out by Malinowski (1922/1987), Mauss (1923/1990) or Evans-Pritchard (1940/1974), a strong point was made that cultural notions, the organization of labour and the circulation of goods are deeply intertwined phenomena.

Leroi-Gourhan (1984) explored the relationships between techniques used by social groups ("external environment") and the range of conceptions available in these groups ("internal environment"). Fernandes (1964/2008) studied the axiological patterns that emerged in Brazil in the transition from a society based on slavery to a capitalist society organized in classes.

In more recent social science studies, the relations between economy and ideology continued to be explored. In these analyses, however, a new element tends to be stressed: globalization. It is claimed that economy and productive activities do

have impacts on expectations, interpretations and hopes held by social actors, and that such impacts can be quite strong in the framework of a globalized economy.

Ulrich Beck (1986/2005) claimed that globalization brings about environmental threats, spreading concerns that go beyond social classes and old social structures. Milton Santos (2000) analyzed the global diffusion of the capitalist technical system, arguing that this "techno-sphere" influences the formation of a "psycho-sphere," defined as a set of aspirations, hopes, ideas and critiques. Scheper-Hughes (2000) detected the emergence of new wishes and personal projects subsequent to the formation of a "global traffic in human organs." Salter (2007) analyzed the contents of hope inserted into globalized networks of stem cell research, which frequently clash with the cultural standards of some countries. Sandall, Benoit, Murray and colleagues (2009) analysed the ideological effects of the professionalization and privatization of maternity service systems.

Clearly, the topic is too broad to be fully reviewed here.[1] The intention of this brief overview is to point out that many social science studies have already explored the relations between economy and ideology, and, more specifically, between globalization and ideology. However, we are still lacking more detailed studies to show, in very concrete ways, the changes, in terms of discourses and opinions, experienced by those people who are engaged in globalized activities. Moreover, it is important to understand how the ideological products of globalization overlap with, or take over, the cultural traditions of particular countries and places. In other words, previous studies on globalization and ideology have not enabled us to disentangle, in people's everyday actions and speech, globalized ideological elements from ideas that are locally available in the form of cultural, axiological traditions. Thus, my study aims to help understand the shifts undergone by the ideological dimension of social life as a consequence of globalization.

In order to carry out this study I draw on the theory of communicative action, proposed by German sociologist Jürgen Habermas. As we shall see in the following chapter, this theory enables us to fully understand the ideological blends provoked by globalization. In terms of empirical topic, I focus on pharmaceutical activity and, more

[1] As explained and justified in the next chapter, the literature review of my specific topic will be gradually presented throughout this thesis.

precisely, the conduct of global clinical trials and the diffusion of the ethics committee model. The reasons for this empirical choice are presented in the following sections.

1.2. Globalization of clinical research

In order to study the axiological consequences of globalization, it is important to select an economic activity that is endowed with a twofold characteristic. On the one hand, this activity must have reached high degrees of internationalization, so that social actors recognize it as a relevant issue in different countries and cities. On the other hand, it must be somehow undergoing changes, so that social actors look at it with interest, discomfort or suspicion, engaging in reflections.

Pharmaceutical activity meets these requisites. Nowadays, medicines occupy an important part of everyday life, as shown by three phenomena. First, many conditions that were not seen as pathological have received the label of diseases, being therefore considered as dysfunctions to be treated with medicines, in a process that has been called "medicalization" (Conrad, 1992). Second, global pharmaceutical corporations have been formed whose operations encompass vast lists of countries (Magalhães, 2003, Bicudo, 2006). Finally, the use of medicines has become so normal that they are sometimes incorporated into non-scientific beliefs and framed as magic products, being expected and hoped to be effective (Fisher, 2009, Lefèvre, 1991, Van der Geest et al., 1996). In addition to having attained such high degrees of normalization and globalization, pharmaceutical activity meets our second requisite: since the 1990s, it has undergone an important shift.

Indeed, if one focuses on the first stages of drug development, a promising field of study is opened up. Over the last years, several pharmaceutical companies have intensified their investments in clinical trials. These trials are studies through which new therapeutic compounds are tested in human beings, in order to verify their efficacy and safety, and eventually, if results are positive, derive new medicines. It is known that in 2008, 60 to 70% of R&D investments made by pharmaceutical and biotech companies were directed to these kinds of clinical tests (Voi Consulting, 2009).

From the pharma companies' standpoint, clinical trials began to become a strategic activity in the 1960s, a period in which a plethora of new compounds was

formulated. According to Epstein (2007, p. 32), the modern clinical trial is "[…] a method of formal experimentation that became prominent only after World War II […]." One of the first trials carried out by a company was a 1956 study undertaken by the British laboratory Searle, which recruited patients in Porto Rico to test a contraceptive drug (Petryna, 2009). At this time, however, clinical studies were not largely conducted, and many companies launched medicines without carrying out very detailed tests on human beings.

In 1962, the US Congress, by amending legislation of the Food and Drugs Administration (FDA), determined that all new therapeutic compounds should undergo clinical studies to have their efficacy and safety assessed (Angell, 2005, Lakoff, 2007, Petryna, 2009, Shah, 2006, Timmermans and Berg, 2003). This event became a watershed in the history of trials. "These new regulations institutionalized the randomized clinical trial as the scientific gold standard in health care, in turn providing the preferred raw material for evidence-based medicine evaluations" (Timmermans and Berg, 2003, p. 166).

Even though this shift provoked an expansion in the number of trials undertaken by the industry, studies remained concentrated in the United States and Europe, where most pharma companies have their headquarters. This scenario only began to change in the 1980s. Since that moment, a series of phenomena have turned the globalization of trials into a feasible project. The following list provides us with a historical summary.

- 1970: the FDA determined that all clinical trials should include the technique of randomization, a research method in which patients are assigned at random to different study arms (Petryna, 2009, p. 23)[2]
- 1987: the FDA authorized drug companies to submit new drug proposals by presenting data collected only outside the United States (Epstein, 2007, p. 197-198, Shah, 2006, p. 7)
- Late 1980s: creation of today's large Contract Research Organizations (CROs), companies that offer clinical-research-related services to pharma companies.

[2] In most trials, there are two arms. One group of patients receive the candidate medicine, while the other group receives a placebo. In other trials, the candidate drug is compared to an active medicine which is already available on the market.

The flexibility offered by CROs has made it easier to globalize clinical trials (Fisher, 2009, Petryna, 2009, Piachaud, 2002, Shuchman, 2007)

- Early 1990s: in tandem with the signature of the Trips agreement and the emergence of the World Trade Organization, the International Conference on Harmonization (ICH) was created, an agreement established between the European, American and Japanese pharmaceutical agencies, aimed to normalize the regulatory frameworks of these three regions
- 1995: the World Health Organization published the Good Clinical Practices (GCP), a range of guidelines to be complied with in the design, conduct, auditing and analysis of clinical studies. Even though these rules are not strictly followed by the industry, they have become an important reference for physician-investigators in many countries (Petryna, 2009, p. 107-108): "[...] for the clinical trials industry, ICH-GCP standards made clinical data from international research sites transferable and acceptable to regulatory bodies in […] major markets. It also would make it easier for a new drug to be registered by different countries and marketed globally" (Petryna, 2009, p. 24)
- Early 1990s: the FDA declared it would consider the offshoring of studies, and the consequent inclusion of ethnic variations into studies, as a positive factor[3]

These phenomena slowly made the globalization of trials become an attractive option from the industry's viewpoint. At the beginning of the twenty-first century, all the key multinational pharma companies were already conducting an important proportion of their clinical studies outside the United States. Wyeth, for instance, conducted 70% of its trials outside the United States in 2006; whereas GlaxoSmithKline conducted half of its studies outside the United States and Western Europe in 2007 (Julie Schmit, quoted by Petryna, 2009, p. 13).

Indeed, the 1990s witnessed a steady and rapid globalization of clinical studies (Epstein, 2007, Fisher, 2009, Petryna, 2006, Petryna, 2009). In addition to the events summarized above, other factors could be invoked to explain the globalization of trials, but it is difficult, if not impossible, to point to a main cause. Elsewhere (Bicudo, 2011), I

[3] Details of these events can be found in the texts quoted. Particularly detailed accounts are presented in Petryna's and Shah's books.

listed some reasons frequently stressed by analysts: lower costs faced by companies in some settings, for some types of studies; the willingness to include an ethnically diverse study population in trials; difficulties of finding patients to enrol in trials in Europe and the United States; among others.[4] Following the globalization of clinical trials, some countries, such as India, China, Brazil or Poland, have become strategic research settings for pharma companies.

Therefore, whenever I speak of global trials in this thesis, I am referring to clinical studies whose conduct involve the participation of two or more countries, whose research centres comply with procedures and standards established by the global management of the study.[5] Even though global trials can be managed by state or non-profit organizations, I am especially concerned with trials sponsored and conducted by the trials industry (pharma companies and CROs). This is so because "industrial" trials tend to be ideologically more controversial (and therefore richer for sociological enquiry) because of the intervention of financial concerns and economic schemes in medical research.

1.3. GLOBALIZATION OF THE ETHICS COMMITTEE MODEL

Many of the regulations and standards that are nowadays in place have been provoked by scandals in the history of clinical research. For example, when the US Congress made the conduct of trials mandatory, in 1962, the main purpose was to forestall the repetition of stories such as the thalidomide scandal, which had been recently unravelled by the media. In fact, the history of clinical research has always been marked by examples of abuses and exploitations, such as the Nazi studies.[6]

As soon as trials became a global phenomenon, new scandals came to light. In 1994, for instance, a study was undertaken in Africa to test the efficacy of AZT to prevent perinatal transmission of Aids (Bayer, 1998, Petryna, 2009). Women who joined the study did not understand it, and placebos were used even in face of the

[4] We shall mention other reasons in the following chapters. As we shall see, depending on the perspective that one adopts to speak of trials, one reason is selected to play the role of "main cause" of the globalization of trials.

[5] I am not drawing any distinction between the following expressions: "clinical trial," "clinical study," and "clinical research." Even though a distinction can be established, it is not important in the framework of my thesis.

[6] We shall come back to this point in Chapter 4.

evidence that the drug was very likely to halt the infection of newborn babies. This case showed that the globalization of clinical trials seemed to offer a huge leeway for scandals to emerge, especially because studies were being transferred to poor countries with illiterate, poor populations.

In order to fight such troubles, the ethics committee model was proposed. An ethics committee is a collective (generally multidisciplinary) body, responsible for receiving research proposals to be undertaken in particular research settings (generally, hospitals, medical practices and research institutions). Committee members must analyse the project by considering its scientific worth, practical feasibility, and ethical soundness, allowing, postponing or refusing the conduct of studies. According to the World Health Organization (2000, p. 1), ethics committees "[...] are responsible for carrying out the review of proposed research before the commencement of the research. They also need to ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision."

Ethics committees were firstly created in the United States, where they are called Institutional Review Boards. First versions appeared as early as the 1920s, being created to deal with specific clinical issues such as sterilization or abortion. However, this period did not witness the creation of many committees, which began to proliferate subsequently. As we did with global trials, let us consider the following list, which summarizes key moments in the ethics committee model's early (American) history.

- 1953: a federal document mandated the presence, in US hospitals, of boards to inspect procedures that, apparently, were not in line with established medical procedures (Eckenwiler, 2001, p. 38-39, Kohlen, 2009, p. 64)
- 1966: the National Institutes of Health published guidelines instructing researchers to let their studies be assessed by a body of specialists not involved in the project (Levine, 1995)
- 1970: federal laws were published mandating the review, by an ethics committee, of every study receiving public funding
- 1971 to 1978: following the publication of many scandals and abuses in clinical research, a National Commission was appointed to cope with problems in

medicine and research. Lately, the group became the so-called President's Commission, which encouraged the creation of committees in hospitals (Kohlen, 2009, p. 65-67, Rothman, 1991, p. 188-189)

- 1974: publication of the US National Research Act, according to which researchers should follow the rules of the National Institutes of Health, submitting all their research projects to an ethics committee for ethical approval (Shah, 2006, p. 75, Epstein, 2007, p. 44)
- 1975: The World Medical Association published the Declaration of Helsinki, stating basic rules and principles for human experimentation. The document prescribed the creation of ethics committees to analyze research projects (Shah, 2006, p. 75)
- 1979: the US President's Commission published the so-called Belmont Report, which contained principles to guide the ethical review of research projects (Kohlen, 2009, p. 67, Lederman, 2006)
- 1980s and early 1990s: committees were diffused in the United States, being formed in most hospitals (Kohlen, 2009, p. 85-88, Rothman, 1991, p. 255)
- Early 1990s: the US Inspector General recommends that the FDA encourages and fosters the creation of ethics committees outside the United States (Petryna, 2009, p. 38)
- 2000: the US National Bioethics Advisory Commission publishes a report stating that studies submitted to the FDA should undergo ethical review both in the United States and the countries where participants are recruited (Petryna, 2009, p. 212 note 57)

Thus, regulatory institutions in the United States, after promoting a successful diffusion of ethics committees in the country, began to encourage the international diffusion of ethics review boards. In addition to these recommendations, the industry itself started asking for committees, insofar as the ethical review of trials would help it prove that clinical studies are fair and accurate. "In order to conform to new global trade rules, countries had to establish new regulatory bodies, mandate ethical review boards, and support a culture of ethics and accountability" (Petryna, 2009, p. 119). Studying the implementation of ethics committees in Germany, Kohlen (2009, p. 95)

concluded that the process amounted to “a re-make of the US-American model of these committees.” Promoting this type of “re-make” in several countries was at least an ancillary aim of US institutions, pharma companies, CROs, and also local administrators.

Therefore, ethics committees have turned into one of the prerequisites to be met by nation-states in order to join the universe of global health research. The history of global trials mingles with the history of the globalization of ethics committees. In my study, I focus on the ideological consequences of this twofold globalizing process. However, in order for my study to be feasible, it is necessary to select particular situations. I propose to focus on the South African and Brazilian situations, for reasons that are explained in the following section.

1.4. Global trials and ethics committees in South Africa and Brazil

As the United States and Europe are regions from where clinical trials have been globally disseminated, most social science studies on global trials and ethics committees focus on these regions. Therefore, it is important to look at these issues from the viewpoint of other countries, where the expansion of global trials has assumed very particular features. My study also aims to help fill this gap in our comprehension of global clinical research. Indeed, I highlight the situations of South Africa and Brazil, two countries that have experienced the globalization of trials as passive receivers, rather than active diffusers, of global pharmaceutical research.

To be precise, the United States is the only country that was able to constitute a *national* ethics review system in the fullest sense of this adjective. In other countries, review systems emerged in the context of globalization and used the American framework as an inspiration. The main difference between the United States and countries like South Africa and Brazil is that in the United States the expansion of trials and the diffusion of ethics committees constituted a slow process, which took many decades, as explained in the previous section. In South Africa and Brazil, the arrival of global trials and the creation of committees underwent a sudden expansion, allowing little time for these countries to adjust to new trends. Thus, as Santos (2000) claimed, we cannot assume the existence of smooth continuities and similarities between the

"scale of ordering" (countries from which globalizing trends spring) and the "scale of doing" (countries targeted by these trends).

Brazil has become one of the key emerging settings for global trials over the last decades. Nowadays, the biggest pharma companies and CROs have offices in the country, which figures in almost all pivotal international studies. Due to fundamental regulatory changes implemented in 1996, this year can be considered a watershed in the history of clinical trials in Brazil. Before this year, as Petryna (2009, p. 159) explains, Brazilian guidelines on clinical trials were vague, and ethics committees were scarce, "isolated and played a 'symbolic function.'" This situation proved politically unsustainable in the face of the rapid expansion of global studies in the country since the early 1990s. On the one hand, concerns were growing about the unethical recruitment of people for international trials. On the other, pressures from international institutions and companies urged Brazil to modernize its regulatory and ethics review system.

In response to these sudden changes, the Ministry of Health, by means of its National Council of Health, published the 1996 Resolution 196, the first Brazilian guideline to address clinical research in detail. Prior to this publication, a multidisciplinary group based in the National Council, and led by physician Willian Saad, promoted a series of debates, involving several sectors of society (pharma companies, patients, hospital administrators, physicians, among others). At the end of this process, the group wrote and published the Brazilian Resolution, which proposed the creation of the National Commission for Research Ethics (Conep, *Commissão Nacional de Ética em Pesquisa*) and encouraged the formation of local ethics committees in hospitals and universities. Saad became the first chair of Conep, which assumed the responsibility for two main tasks. On the one hand, the Commission oversees the work of local ethics committees. On the other, it became responsible for reviewing research projects in the so-called "special areas" (*áreas especiais*), which include genetic studies, research with foreign funding, studies on new medicines, studies involving indigenous populations, among others. Thus, every study classified as a "special area" must go through a two-layer process, being reviewed by both Conep and the local committees of research sites where participants are recruited.

Highly informed by bioethical concerns,[7] the group that published the Resolution 196 wished to formulate very broad guidelines, in order to encompass every kind of study involving human beings. In 2005, Saad, still chair of Conep, recalled the publication of the Brazilian Resolution by saying: "We thought not only of medical research but of how to do a Resolution pertaining to human beings while preserving and protecting its aspects in terms of health" (Saad, 2005).

By this period, clinical trials had become a thriving activity in Latin America (Dainesi and Elkis, 2007). It is known that, in the late 1990s, the region was displaying the world's most intense expansion in terms of global trials (DataEdge, 2001). Brazil, as a regional economic leader, appeared in an outstanding position. From 1995 to 2001, investments in clinical trials underwent a 411% rise in the country (Bicudo, 2006). The presence of good research infrastructure and high-skilled researchers, as well as the modernization of the regulatory system, help to explain such an astonishing growth (Bicudo, 2006, Petryna, 2009). In certain medical specialties, such as cancer or heart diseases, Brazil has internationally renowned institutions and physician-investigators. Hence, the rapid expansion of trials in some specific fields, as exemplified by Silva and collaborators' (2011) study focusing on transplant-related trials. However, most global trials were concentrated in the southern part of the Brazilian territory. Nowadays, some global CROs have 50% of their studies installed in only two cities: São Paulo and Porto Alegre, which have become the main hubs of clinical research in Brazil.

The expansion of global trials in South Africa has been more modest than in the Brazilian case. This fact is understandable if we consider that according to estimates of the United Nations (2011), the Brazilian population is more than four times bigger than the South African population, and according to the International Monetary Fund (2011), the Brazilian economy is more than seven times bigger than the South African economy, in terms of GDP. Nevertheless, South Africa has also been targeted by the globalizing trends of the 1990s. One of the reasons is the vast population of HIV-infected people in the country, accounting for 17% of the national population in 2008, according to the United Nations. Thus, South Africa turned into an inescapable setting for the study of anti-retroviral drugs. Nowadays, all big pharma companies have their units there and, in the case of CROs, the country is frequently their only location in the

[7] On this point, see Chapter 4.

entire African continent. Thus, CROs have selected South Africa to be a regional headquarter, from which the operations of representatives based in other African countries are managed.

In spite of the relatively modest weight of the South African economy, the country's participation in global trials is worth noting. "According to an article in the July 2003 edition of the 'CRAdvisor Newsletter', a South African Department of Trade and Industry Survey, conducted in 2000, revealed that South Africa is currently awarded 0.6% of the world's clinical research contracts from international research companies and clinical research organizations (CROs), and has the capacity to conduct 2.5% of the current global work" (Baird and Van Niekerk, 2004, p. 33).

Like Brazil, South Africa could attract global trials due to its appropriate medical environment. In the 1960s, some South African hospitals already had sophisticated infrastructures, like the Groote Schuur Hospital in Cape Town, where the world's first heart transplant was performed in 1967. However, this dynamics was limited to a small number of hospitals, in areas from which most people were excluded. With the end of the apartheid regime in 1994, these geographical inequalities have been fought by means of modest national policies. Even though important clinical hubs can be found across the country (in cities like Durban, Port Elizabeth and Cape Town), the most important sites continue to be concentrated in the province of Gauteng, and mainly the cities of Johannesburg and Pretoria (where most of the South African population lives). By 2003, as explained by Shah, many CROs were operating in the country, targeting especially the most developed hospitals and universities. "At institutions like the University of Stellenbosch drug companies would soon be proposing over sixty new trials every year" (Shah, 2006, p. 104).

The Medicines Control Council is the agency that oversees pharmaceutical production and registry in the country. It was founded in 1965 but its current organization is not very old. "South Africa first implemented GCP guidelines in 2000 and updated them most recently in 2006" (Voi Consulting, 2009, p. 26). In 1996, by means of the National Drug Policy, the country signalled its willingness to modernize its regulatory framework. However, the required complementary law, called Act 59, was approved only in 2003. In the same year, the South African Parliament approved Act 61, known as the National Health Act, restructuring the health system. One of the key measures was the creation of the National Health Research Ethics Council

(NHREC), which became the central agency responsible for overseeing the ethics review system. Contrary to what happens in Brazil with Conep, the NHREC does not review research projects, being only responsible for establishing ethics guidelines and monitoring the local ethics committees' operations. As the legal text puts it, the NHREC must, among other functions: "set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials" (Parliament of South Africa, 2003, p. 74).

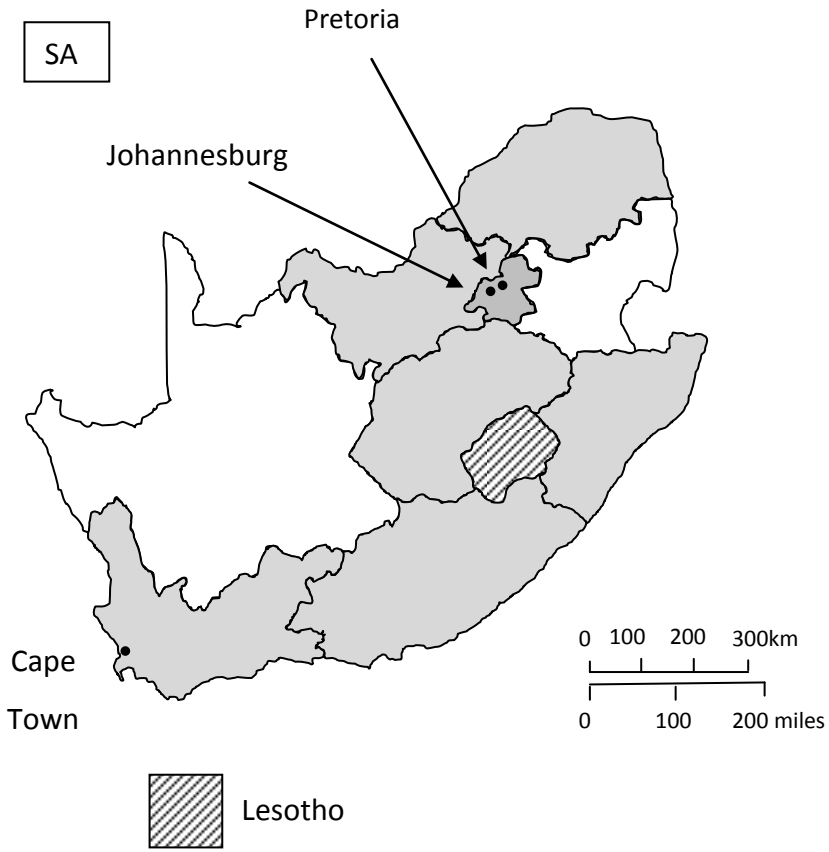
Under the sway of globalizing trends, both South Africa and Brazil had, therefore, to implement relatively quick adjustments in their institutional and legal frameworks. One of the most pressing needs was the constitution of a national review system based on ethics committees. Shaken by the liberalizing trends that prevailed worldwide in the 1990s, both countries entered the twenty-first century trying to modernize their economies and acquire relevant positions in the international scenario. Participation in global trials was seen as an appropriate strategy to help reach these goals. As a consequence, it was necessary to provide foreign regulatory agencies, and especially the trials industry, with the institutional structure that was required. In 2001, both countries had already joined the International Conference on Harmonization (ICH) and Good Clinical Practices (GCP), with the implication that they should constitute their ethics committee system, for as Petryna (2009, p. 159) claims, the ICH-GCP framework "includes guidelines for institutional review boards."

On this point, the two countries adopted different solutions. In Brazil, Resolution 196 encouraged the proliferation of ethics committees, stating that: "Institutions where studies involving human beings are undertaken shall constitute one research ethics committee or more, depending on their needs" (Conselho Nacional de Saúde, 1996). In South Africa, the National Health Act stated that: "Every institution, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee [...]" (Parliament of South Africa, 2003, p. 76). By allowing research sites to simply "have access to" an ethics committee, rather than establishing their own committees, the South African law made the diffusion of reviewing boards less intense than in Brazil. In 2011, South African NHREC registered 30 committees in the whole country, whereas Brazilian Conep, in the same year, registered 608 committees, a number that at the

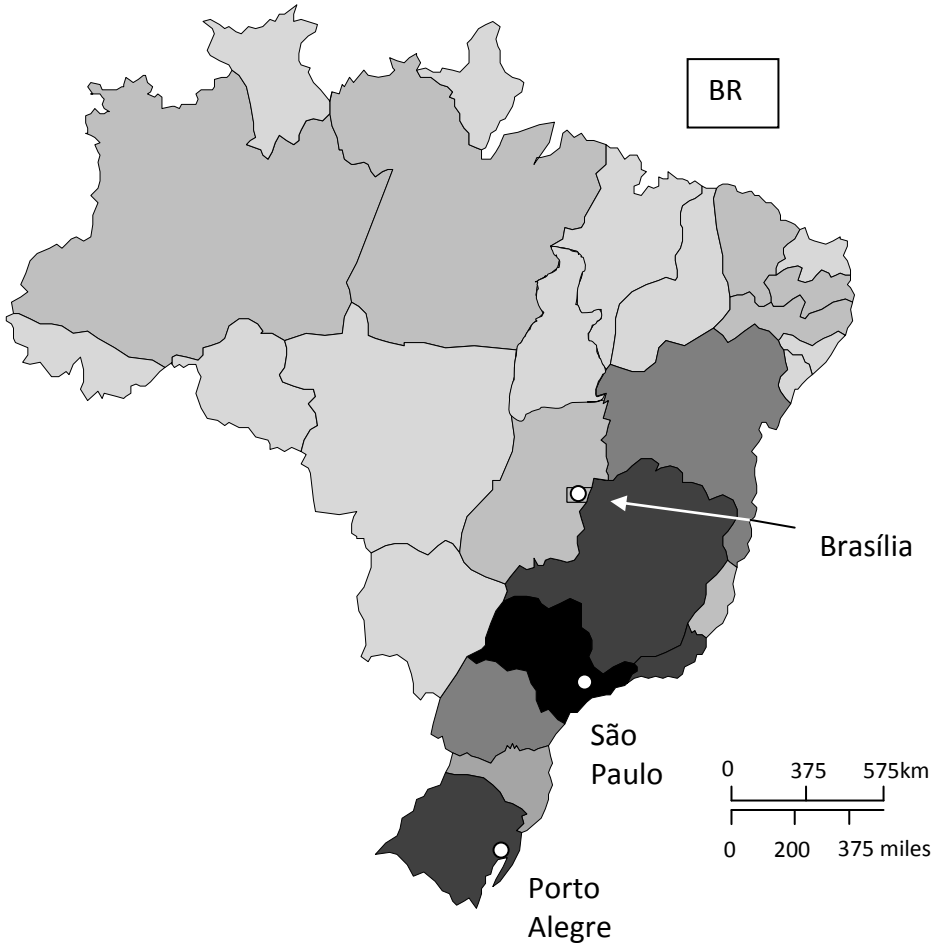
time of my fieldwork was still growing every day.[8] The following maps show the spatial distribution of ethics committees in both countries.

[8] These figures were provided by NHREC and Conep during my fieldwork.

Map 1.1. Spatial distribution of ethics committees in South Africa (30 committees): 2011



Map 1.2. Spatial distribution of ethics committees in Brazil (608 committees): 2011



Number of ethics committees

0 | From 1 to 10 | From 11 to 30 | From 31 to 50 | From 51 to 70 | 166

Source: elaborated by the author with data from NHREC (fieldwork) and Conep: http://conselho.saude.gov.br/web_comissoes/conep/index.html

As the maps show, the geographical inequalities of Brazil are reflected in the ethics review system. Most committees are concentrated in the economically dynamic southern states, with 166 agglomerated in the state of São Paulo and 70 committees in its northern neighbour, Minas Gerais. Generally, the states with less than 31 committees do not receive global trials, holding only academic studies conducted by local researchers. In South Africa the distribution is more balanced than in Brazil, but the province of Gauteng occupies an outstanding position, with 13 committees, followed by the Western Cape (where the city of Cape Town is located) with 6 committees.

In Brazil the most important research sites are situated in state universities, which have their own committees. South African universities and government hospitals are also key research sites, but private practices and hospitals play an important role as well. Generally, these private sites do not have ethics committees, and contract the reviewing services of two private committees located in Pretoria. These two private committees, which are organized as companies receiving fees for their tasks, are the only boards with these features in the country.[9] As a consequence, private committees (an institutional form which is absent in Brazil) play a pivotal role in the South African review system.

To summarize, since the 1990s South Africa and Brazil have undergone decisive changes as a consequence of efforts spent mainly in the United States, "exporting the IRB [Institutional Review Board] model," to use Petryna's (2006, p. 55) words. As I claimed at the beginning, the globalization of trials and ethics committees is arguably provoking crucial changes in the ways in which social actors frame and interpret social issues. My study, by focusing on the South African and Brazilian contexts, aims to unravel the nature of these ideological processes, as explained in the following section.

1.5. AIMS AND QUESTIONS

According to Braun (2005), several sorts of ethics committees have been diffused throughout the Western world over the last decades in order to deal with

[9] As we shall see, one of these committees took part in my study.

issues brought about by the development of medical technologies. By 2009, for instance, the ethics committee model had been largely adopted even in sub-Saharan Africa, a world region with a relatively small number of clinical studies (Nyika et al., 2009). This phenomenon implies not only the diffusion of a certain sort of institutional form but also the necessary proliferation of a new type of social actor: the ethics committee member. Nurses, physicians, lawyers, bioscientists, among other professionals, are mobilized to engage in the review of research projects that are frequently submitted by multinational companies. Thus, a group of actors becomes involved in issues whose scope goes beyond their immediate local and national contexts. By entering in contact with bioethical guidelines, meeting other professionals in the regular committee meeting, being confronted by cutting-edge research methods, or learning the procedures and particularities of global trials, these professionals cannot avoid being exposed to new sets of discourses, ideas, explanations and ideologies. At the same time, they must look at these emerging ideological elements in the light of beliefs and notions they have carried for long years. For these reasons, ethics committee members constitute an invaluable group for those who wish to understand the ideological combinations and shifts made possible by the globalization of clinical trials.

According to Milton Santos (1979/2003), under-developed countries, by installing technological infrastructures imported from central countries in the 1970s, ended up putting their geographical configuration at the disposal of an international political project elaborated outside of their territories. If material infrastructures can carry political projects, it is worth asking if the importation of institutional forms, such as ethics committees, can also have impacts on the political and ideological dimensions of a country. The answer seems to be positive, for as Petryna (2009) explained, many countries adopted the ethics committee model in an attempt to realize a requisite of institutional efficiency and rapidity which was in tune with multinational companies' aspirations.

Another clue is offered by Lakoff (2005), who showed how the globalization of trials depends on previous diffusions of some cognitive frameworks, such as medical standards making it possible to compare and commensurate health conditions by using scales and diagnosis methods. However, we are still lacking interpretations to show how these broad ideas (such as efficiency and institutional swiftness) are assimilated

and processed at an individual level. Moreover, it is important analyze how this individual understanding is channelled back into the political life of national institutions. These are also aims of this thesis.

It is crucial to point out that my study has not only a philosophical but also a sociological and political relevance. The diffusion of certain ideologies frequently underpins the adoption of certain political projects. For example:

> "Today insubstantial promises, which are based upon a potential that is difficult to assess properly and which will take time to develop fully but which are amplified through the media, excite the imagination of industry and the public and influence decisions about which parts of basic research are to be funded and which lines of inquiry are to be pursued (although, in 'objective' scientific terms, one may seem just as promising as the other). Collusions of interest emerge almost unaided which tread a thin line between authentic belief in the future potential and mere rhetoric of 'selling' a particular line of research to politicians and the public" (Nowotny et al., 2001/2007, p. 38).

However, the contact with technical and institutional forms diffused by globalization may also trigger resistances. In this way, social actors, instead of accepting trends and ideas spread by global actors, may refuse them and look for alternatives. That is why, as Certeau (1990, p. 79) claimed: "It is impossible [...] to reduce the operations of a society to a dominant type of procedures." From this point of view, ethics committees constitute an arena crossed over by several political ideologies, being therefore similar to scientific advisory committees, whose meetings "[...] serve as forums where scientific as well as political conflicts can be simultaneously negotiated" (Jasanoff, 1990, p. 237). In this way, discourses voiced by ethics committee members would constitute, at the same time, specks of culture and specks of political projects. "Culture, here, is not cults and customs, but the structures of meaning through which men give shape to their experience; and politics is not coups and constitutions, but one of the principal arenas in which such structures publicly unfold" (Geertz, 1973, p. 312). Thus, by looking at ethics committees, we can see culture and politics being enacted and actualized by concrete social actors.

Depending on the standpoint chosen by ethics committee members, the meaning of global trials, pharmaceutical research, and national health policies can vary immensely. Even though they are all supposed to carry out an "ethical" assessment of research proposals, the precise scope of this adjective has not been (and maybe cannot be) precisely determined. As Braun (2005) pointed out, people attribute very different meanings to the concept of "ethics." Thus, for a study that focuses on globalization and ideology, the example of committee members constitutes a rich topic, for two main reasons. Firstly because, as I have just claimed, they participate in meetings in which the viability and worth of research proposals are discussed. Therefore, they must, to a greater or smaller degree, engage in what Arendt (1963, p. 82) described as the "[...] wearisome processes of persuasion, negotiation, and compromise, which are the processes of law and politics." Secondly, debates about clinical trials belong to the professional life of committee members who are, consequently, likely to end up formulating a discourse about trials, pharma companies, CROs, among other topics, thus going beyond a simple commonsense view.

This second point is crucial. Indeed, as committee members tend to formulate these structured views about clinical trials, a discourse analysis can be undertaken in order to grasp the discursive elements and structures that are being marshalled. Conducted with accuracy and imagination, this analysis can unravel the ideological changes, upheavals and resistances entailed by the globalization of trials and ethics committees. Thus, it is possible to realize that, even though "globalization" (in the singular) is generally fostered by one single economic and technical rationale, the ideological responses it generates allow us to identify different "globalizations" (in the plural), for people never cease to attribute different meanings to the same events.

I thus present the main questions of this thesis as follows:

- Does the globalization of trials lead to a sort of ideological harmonization, in the sense that people start adopting the same views and discourses regardless of their geographical contexts and social lifestyles?
- Can ethics committees be seen as a sort of global community, in the sense that committee members share an ideological framework?

- Is the political and economic power of pharma companies and CROs somehow underpinned by ideological processes?
- How important are national characteristics for people who are systematically concerned with global procedures and processes?

From these questions, another set of more specific goals can be derived:

- What are the rationalities expressed by committee members? How could we describe and name these rationalities?
- Is it possible to identify, in one person's discourse, different composing elements? Can we describe the philosophical and social history of these ideological components?
- In spite of the social, geographical and economic differences between South Africa and Brazil, can we identify similarities in the discourses voiced by ethics committee members in these countries?
- Is there any type of rationale that is promoted and diffused by trials companies? How would such transmission happen? How could we describe this rationale?
- Is it really possible to claim that ethics committees are political arenas in which divergent ideologies struggle for ideological legitimacy?

In order to address these questions, I am presenting a text organized in the following fashion. In the second chapter, I shall present the research methods used in my study. The actual analysis begins in Chapter 3, where I first introduce the concept of *mentalities* and describe the first approach to clinical trials, named *pragmatic mentality.* Chapter 4 presents two more *mentalities* (called *bioethical* and *communitarian*). The description continues in Chapter 5, in which the *technical* and *analytical mentalities* are focused on. The two final *mentalities* (named *healing* and *critical*) are presented in Chapter 6. Finally, the general Conclusion retakes and explores central ideas presented in the previous chapters.

As the historical descriptions of this Introduction have shown, global trials sprang from some countries (the headquarters of pharma companies) to other countries; regulatory agencies, which have a national scope, played central roles; and the ethics review system has always assumed national (rather than regional or international) features. Therefore, the national state and all the legal instruments associated with it are decisive in our analysis. As Habermas explained, there is permanent communication between the national legal dimension and the everyday communicative negotiations undertaken by individuals in their search for constitutional rights. “Because these rights must be interpreted in various ways under changing social circumstances, the light they throw on this context is refracted into a spectrum of changing legal paradigms” (Habermas, 1996, p. 387). Therefore, the comprehension of political and legal trends depends on the comprehension of everyday communicative practices, and vice-versa.

In order to see these combinations between individual, national and global dimensions, it is crucial to look for mediations. Ethics committees can be framed as mediating institutions. On the one hand, they are located at social positions that Habermas defined as the “periphery” of the political system, because they are composed by citizens who master the basic cultural tools of a country. On the other hand, ethics committees have some contact with what Habermas (1996) called the “core area” of the political system, because in addition to being composed by many scientists and experts, they are directly linked to national agencies and Ministries of Health. In the light of the South African and Brazilian situations, therefore, I try to unravel the ways in which these individual, national and global scales have been associated over the last years.

Chapter 2 – Methodology

As explained in the Introduction, my study has cultural and political dimensions. In addition, we will be dealing with complex issues (clinical trials and ethics committees) that have been targeted by debates and legal changes in two different countries (South Africa and Brazil) and two different world regions (Southern Africa and Latin America). In order to cope with all these aspects, it was necessary to choose flexible strategies of research, analysis and final exposition. In this chapter, I introduce my main theoretical basis, analytical tools and strategies pertaining to literature review. Firstly, I describe the theory I draw on. Secondly, the ways in which I approach literature will be explained. After describing the methods used to prepare and conduct the fieldwork, I explain how my interviews were analyzed. Finally, I describe the statistical tools I utilized.

2.1 SOCIAL ACTIONS, RATIONALITIES, AND ETHICS COMMITTEES

In my study, I draw on the theory of communicative action proposed by German sociologist Jürgen Habermas (1981/1987, 1996) in the early 1980s. The use of this theory is due to three reasons. Firstly, even though social theories help us interpret particular cases, they are primarily aimed to explain broad processes and trends. It seems to me that Habermas' theory is endowed with the capacity to explain several phenomena taking place in contemporary society. Secondly, the globalization of trials seems to imply a division between notions that tend to be globalized and traditional ideologies that are generally embedded in local contexts. As we shall see, Habermas' theory points to a basic division that can be applied to this dual nature of global trials. Finally, ethics committee members are engaged in constant communicative processes, insofar as they analyze written documents and discuss research projects with their colleagues. Thus, it seems appropriate to look at these social actors from a communicative point of view.

As any sociological explanation wishes to do, Habermas' theory aims to explain the ways in which people create conditions for living together. The basic idea is that by means of social actions, people can not only realize practical tasks but also convey, recognize and negotiate meanings. Social action implies communication, and this is why one speaks of "communicative actions."

Claiming that actions contain communication amounts to recognizing a twofold process. On the one hand, social actors must pay attention to established rules, predetermined meanings and possible statements, for actions are always socially limited. On the other hand, there is a content of freedom in communicative actions, for they are used in order to engage in negotiations and therefore reach states of mutual agreement (Habermas, 1981/1987, Habermas, 1996). However, it is important to consider that depending on their purposes and resources, social actors can undertake their actions in two different ways. More precisely, they can express two different rationalities.

Some actors are more resourceful and have the capacity to shape and modify the surrounding conditions, including other actors as well as material means. For these actors, it is crucial to strive to modify the worldly conditions in order to realize a "strategy." In this way, these actors frame and use the surrounding conditions as a means, a tool, an "instrument." This is why one can talk about an "instrumental rationality."

> "We name *instrumental* one action oriented towards success, when we consider it from the point of view of the pursuit of technical rules of action and when we assess the degree of efficiency of an intervention in a context of state of things and events [...]" (Habermas, 1981/1987, p. 295).

Therefore, *instrumental rationality* presupposes the existence of a plan, a project, as well as the capacity to shape the surrounding world in order to realize this project. *Instrumental actors* are always searching for targets and trying to reach success.

On the other hand, there is a set of actors who are not able to realize the requisites of *instrumental action.* For these actors, the surrounding conditions are not seen as means of actions but as elements with which one's actions have to be

harmonized. Here, the main intention is no longer the realization of a strategy but the search for "intercomprehension." It is necessary to undertake negotiations and look for agreements so that different actions can be combined through communicative processes. Therefore, one identifies *communicative actions.*

> "[...] I speak of *communicative actions* when the action plans of participant actors are not informed by egocentric calculations of success but by acts of intercomprehension" (Habermas, 1981/1987).

However, it is crucial to understand that the concepts of *instrumental* and *communicative rationality* do not refer to personal and psychological stances. As Habermas (1981/1987, p. 296) explains: "[...] this elucidation should not be understood as a psychological task. I do not aim to characterize behavioural dispositions empirically, but to grasp general structures of processes of intercomprehension [...]." Therefore, the theory of communicative action focuses not so much on personal motivations, but on states of things and social contexts. Even though Habermas does claim that instrumental actors hold egocentric projects, the fundamental aspect of their actions is not this egocentric stance but the fact that they can frame social contexts as *instruments.* This is why one speaks of *instrumental,* rather than egocentric, *action*.

In the framework of my study, it is important to point out some basic traits of these two *rationalities.* Firstly, instrumental actors pursue specific targets, which become their main concern, whereas everything else tends to be regarded as simple tools. In order to realize their strategies, instrumental actors can impose their views either "[...] instrumentally, by influencing the action situation directly, or strategically, by influencing, through calculations, the decisions of their counterparts." In this way, instrumental action frequently mobilizes general concepts and patterns of behaviour so that their plans can be realized in different social conditions. In their turn, communicative actors can never impose projects, insofar as intercomprehension is paramount and "[...] agreements cannot be induced and exercised from outside but has to be accepted as valid by the participants" (Habermas, 1981/1987, p. 297). Thus communicative actors must always take into account the particular features of their social contexts.

Secondly, one could argue that the *instrumental rationality* is wordly whereas the *communicative rationality* is mundane. On the one hand, the calculations undertaken by instrumental actors take into account the established, fixed conditions of the world. Without these considerations, projects would rapidly prove unviable and unsuccessful. On the other hand, intercomprehension never derives from rigid processes; rather, it is something that must be created through the communicative act itself. Therefore, communicative actions are certainly based on material and practical conditions but they always strive to go beyond such conditions and bring about new elements to the world (Habermas, 1981/1987, p. 302-303).

However, when focusing on the individuals' point of view, the broad idea of *rationality* cannot fully explain ideological processes. This conceptual limitation is explored in the following chapters, in which I propose to solve this theoretical limitation by introducing the concept of *mentality.*

2.2 APPROACH TO LITERATURE

In my study, I strived to conduct a very detailed analysis of my interviews, delving into the structures of my interviewees' discourses. This careful examination is necessary in order to look at individual discourses in the light of debates taking place in society. According to Geertz (1973, p. 313): "Each study struggles to draw broad generalizations out of special instances, to penetrate deeply enough into detail to discover something more than detail." The study of ethics committees allows us to realize these passages because as claimed by Kohlen (2009, p. 135), committees are situated at an "institutional level," mediating between the "individual level" (moral decisions) and the "societal-political level" (institutions and public agencies).

Realizing these passages with success requires an active analysis of discourses. In other words, it is necessary to grasp the meanings invoked by committee members in the light of the concepts offered by the theory I am mobilizing here. In this way, the aim is to carry out a cultural analysis such as the one proposed by Geertz (1973), in which the anthropological text *converses* with the speeches voiced by the "natives" studied. To put it with Denzin's (1997, p. 41) words: "A written text becomes a

montage (and a mise-en-scène) – a meeting place where 'original' voices, their inscriptions (as transcribed texts), and the writer's interpretations come together."

My purpose is to make my interpretation *converse* not only with my interviewees' discourses but also with the authors and interpreters I quote. In this way, it is important to note that throughout my text, authors will be quoted in three different ways. Firstly, some authors (such as Petryna, Fisher and Epstein) will be quoted as sources of information and data about clinical trials. From these studies come relevant examples that underpin my analysis, even though these examples are adjusted to fit into a different theoretical framework.

Secondly, some authors will be quoted as examples of *claims* expressing *mentalities.* In these circumstances, there will be no difference between these authors' claims and the claims voiced in the interviews I conducted. For example, if we focus on a typical *bioethical* claim (like "research subjects must receive full and clear information about their participation in research"), it is easy to see that many authors, in their studies on clinical trials, came to express this bioethical view. In this way, I will refer to these authors in Chapter 4, when dealing with the *bioethical mentality.* This is why this thesis lacks a chapter called "literature review." In order to make my exposition clear and coherent, it proved to be more interesting to spread my literature review throughout my text, grouping different authors according to the *mentality* favoured by their interpretations.

Thirdly, there is a group of texts and ideas that I quote in order to underpin my interpretation theoretically. Therefore, this thesis is punctuated by several "interventions" from authors such as Habermas, Arendt, Geertz, Santos, Certeau, among others. As explained before, Habermas provides me with my principal theoretical framework, by means of his communicative action theory. The choice of other theoretical contributions was made, mainly, on the basis of their suitability for a communicative explanation. In a certain sense, these authors' theories enable us to look at society and space in the light of communicative processes.

Milton Santos, in his geographical theory, explored the consequences of globalization for non-central countries. He stressed the formation of "spatial densities" as a result of the globalizing process. In addition to "technical," "scientific" and "informational densities" in some places and cities, one can identify the emergence of "communicational densities" characterized by the formation of contexts in which

human contacts and the circulation of news are facilitated. Thus, his theory helps us to see some situations (as well as some bodies like ethics committees) as favourable places for communication to take place.

Certeau's philosophical work explored the appearance of unexpected social rationales in the interstices of the dominant capitalist logic. According to him, this phenomenon has to do with the construction, by the users of the city, of alternative ways to grasp and interpret urban reality. Certeau's theory, therefore, enables to investigate ethics committees as bodies in which unexpected rationales can emerge in spite of the force of dominant ways to frame clinical research.

Arendt's work is quoted by Habermas himself at decisive points of his texts. The main idea that comes from Arendt's work is a definition of social action that enables a communicative approach. The social actor is framed as someone who initiates a dialogue whose future development cannot be foreseen. In addition, Arendt advanced many philosophical ideas that help to build up the communicative interpretation looked for in this thesis. For instance, she claimed that "[...] whatever men do or know or experience can make sense only to the extent that it can be spoken about" (Arendt, 1958/1998, p. 4).

Clifford Geertz has become widely famous by his important linguistic, semiotic interpretations of culture. According to him, culture is at the same time an active and passive phenomenon, insofar as it is constructed by social actors who will subsequently live under the strong influence of their own cultural constructions. Thus, Geertz' ideas allow us to look at ethics committees as bodies composed by actors that build up interpretations, being at the same time conditioned by the force of their ideological creations.

The concept of mentality, which is at the core of my thesis, comes from Simmel's theory. According to Simmel, social actors are constantly giving ideological responses to the manifold stimuli they get from their urban environment. Thus, sociological and cultural analyses must focus not only on practical actions but also on the ideological products of social life. This is a major inspiration for my thesis, which certainly constitutes an effort to apply Simmel's idea to the contemporary period.

In the following section, I describe the organization and conduct of my fieldwork.

2.3 FIELDWORK AND RESEARCH METHODS

In my study, I look at global clinical trials from the viewpoint of ethics committee members. The goal is to identify the meaning (or meanings) imparted by these social actors to issues pertaining to clinical trials. Because of this communicative and semiotic approach, it does not seem appropriate to use the so-called grounded theory, which, as explained by Charmaz (2003, p. 258), generally disregard the controversial dimension of social phenomena, suggesting that "[...] data have an objective status."

Therefore, the actual discourses voiced by committee members acquire a decisive worth in my approach. Hence the choice of individual interviews. As Rubin and Rubin (1995) explained, interviews are not suitable for identifying concrete actions and preferences but are of great importance when it comes to identifying what actors think about their actions and preferences.

It might be argued that discourses voiced by people may not express their actual thoughts and feelings, being used, rather, to deceive and bewilder. From a sociological point of view, this circumstance does not pose any problem, as the main purpose of sociological analysis is not to grasp the individuals' inner reality but to understand patterns of communication and relationship. Thus, even though speakers do not disclose true feelings and thoughts, they certainly voice discourses that are socially meaningful. To use Todorov's (1984) distinction, what matters in sociological/cultural analyses is not "truth" (the disclosure of the inner universe) but "verisimilitude" (the expression of messages that make sense within a certain social context). Therefore, there is no need to look for natural, genuine interpretations, for as Geertz (1973, p. 15) teaches us, interpretations are always "fictions," "[...] in the sense that they are 'something made,' 'something fashioned' […] not that they are false, unfactual, or merely 'as if' thought experiments."

Thus I avoided what Silverman (2001, p. 287) called "naive interview," which takes place when the interviewer considers the interviewee's point of view as an explanation. It is important to convey the precise import I am attributing to individual verbal discourses. These latter, in the framework of my interpretation, are relevant because of two characteristics. On the one hand, claims voiced by particular individuals realize a historical mediation, for they are expressed with words and notions

formulated in the past while being advanced in a particular moment in the present. In Hacking's (1990, p. 8) terms: "Sentences have two powers. They are eternal, and they are spoken by flesh and blood." On the other hand, verbal discourses realize a social mediation, for they are shaped by the local contexts in which they are voiced, being also informed by broad debates taking place nationally or even globally. In this sense, verbal discourses, when carefully analyzed, are endowed with the revelatory capacity that Geertz (1973, p. 23) identified in "small facts": "[…] where an interpretation comes from does not determine where it can be impelled to go. Small facts speak to large issues […] because they are made to."

My research project consisted in using two principal research instruments: interviews with committee members and the observation of regular committee meetings. Through the readings undertaken in this PhD's first year, I became familiar with the idea that in some ethics committees, institutional hierarchies can play a decisive role, an issue that is underlined by some authors (Eckenwiler, 2001, Kohlen, 2009, Rothman, 1991). According to these interpreters, some committee members (especially laypeople) can feel somehow intimidated while discussing issues pertaining to clinical trials with other members (especially physicians). Thus, in order to make sure that my interviewees would speak freely and with no intimidation, I decided to conduct individual rather than collective interviews. Focus groups would not have been helpful either, for my aim was to delve into my interviewees' discourses and, as explained by Fern (2001), in focus groups people frequently get distracted by interruptions and therefore much information can be lost. Even though I focus on individual discourses, I am interested in global processes; thus, it would not have been completely appropriate to conduct case studies, which always stress the individual example, as explained by Stake (2003).

Thus, one of the main tasks to be accomplished in my study was to verify the expression and organization of discourses pertaining to global trials. It was clear that such verbal expressions can also emerge in committee meetings, in which members are supposed to present and discuss particular research proposals. Therefore, my observations were aimed, on the one hand, to verify the ways in which ideas and claims are advanced by members when engaging in the ordinary discussions of projects; on the other hand, observations enabled me to detect some non-verbal signs

that influence the members' attitudes in meetings, thus contributing to a non-verbal discussion.

One of the main tasks of my PhD's first year was to identify and contact key ethics research committees in South Africa and Brazil, inviting them to join my study. As for Brazilian committees, the choice of potential participants was easy because I had previously conducted a Master's study that focused on the pharmaceutical production in Brazil and in which clinical trials appeared as an ancillary topic (Bicudo, 2009). Thus, I was aware of the main research sites in Brazil. As for South African committees, the identification of relevant institutions was undertaken through my literature review, insofar as some papers, reports and books on clinical trials sometimes mention key sites. In addition, I used the website *clinicaltrials.gov* to verify what the South African institutions are which generally take part in trials sponsored by pharma companies. After many months of contacts, explanations and some negative replies, I received positive answers from four Brazilian and three South African committees. After receiving ethical approval from King's College ethics committee, I began the fieldwork in Brazil in March 2011.

Parallel to my PhD, I started another research project called "Finding participants for global trials: recruitment companies in the UK, Spain, France, Brazil and South Africa." This project focused on the organization of global trials, and particularly the strategies used for recruiting research subjects, in these five countries. With a travel grant from the European Science Foundation (Drugs Exchange Program), I conducted interviews with different professionals engaged in global trials in Spain and France, completing the study with other interviews in the UK, Brazil and South Africa. Therefore, in my fieldwork in South Africa and Brazil, I interviewed committee members for my PhD study, as well as other professionals for the parallel project.

Thanks to these parallel interviews in Brazil, I could verify that nowadays, the Brazilian city of Porto Alegre has become a research hub, displaying the biggest expansion, in terms of clinical trials, over the last years. Thus I tried, and managed, to include another committee, based in Porto Alegre, into my PhD study. I also realized successful contacts with Conep, the national ethics agency of Brazil, being able to include it into my study as well.[10] At that point, I had had positive answers from six

[10] With consent from Conep, the members interviewed, and King's College ethics committee, this is the only committee that is identified in my study. This is so because the discourse of Conep's members has a

Brazilian committees. In order to look at each case more accurately, avoiding too superficial views, I decided to exclude one of these committees from my fieldwork. Here, the criterion I used was purely practical: the committee excluded is located in a city that is somewhat distant from São Paulo, where I was based. The Brazilian fieldwork lasted three months (March to May 2011), involving observations in three committees and 25 interviews.

The fieldwork in South Africa started in June 2011. Here, there were no changes: all the committees that initially agreed to take part were studied in my fieldwork. However, another practical issue had to be addressed in South Africa. I was based in Cape Town, where two committees focused on in my study are situated. The third committee is in Pretoria, which is far away from Cape Town. The solution I found was to study this committee in one single day. Thus, I interviewed three members in the morning, observed the meeting in the afternoon, and conducted a fourth interview in the evening. The whole activity lasted about 10 hours. At the end of a three-month stay in South Africa (June to August), I observed meetings in all three committees, and interviewed 17 members.

Committee members joined my interviews in three ways:

1. By spontaneously responding to a collective invitation circulated by email by the committee chair
2. By being personally invited by me, either by email or telephone
3. By being approached by me in the committee meeting

Strategy 1 enabled committee members to spontaneously join my study whereas with strategies 2 and 3, I could select people in terms of professional background and the role they played in the meetings, thereby diminishing the risk of volunteer bias posed by strategy 1. The second strategy came to be the most successful, for it allowed me to obtain the biggest numbers of interviews in all the committees studied.

The following tables present a summary of my fieldwork.

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different nature and content, as they are based in a national commission rather than a local committee. However, I am not disclosing any of my interviewees' names.

Table 2.1 – Summary of the fieldwork: interviews in Brazil and South Africa (March to August 2011)

	Interviewees										
Country	Lay members	Nurses and social workers	Social scientists	Psychologists	Bioethicists	Lawyers	Natural scientists	Pharmacists	Statisticians	Physicians	TOTAL
Brazil	1	2	2	2	2	3	3	2	0	8	25
South Africa	1	2	4	0	1	1	1	1	1	5	17
TOTAL	2	4	6	2	3	4	2	3	1	13	42

Table 2.2 – Summary of the fieldwork: interviews in Brazil (March to May 2011)

	Interviewees					
Committee	Lay members, nurses & social workers	Social scientists	Bioethicists & lawyers	Bioscientists	Physicians	TOTAL
C1: public university, São Paulo	0	0	1	1	1	3
C2: public hospital, São Paulo	2	1	0	0	2	5
C3: public university, São Paulo	1	2	1	2	3	9
C4: Conep, Brasília	0	0	1	2	1	4
C5: private hospital, Porto Alegre	0	1	2	0	1	4
TOTAL	3	4	5	5	8	25

Table 2.3 – Summary of the fieldwork: interviews in South Africa (June to August 2011)

	Interviewees					
Committee	Lay members, nurses & social workers	Social scientists	Bioethicists & lawyers	Bioscientists	Physicians	TOTAL
C6: public university, Cape Town	1	0	0	1	4	6
C7: public university, Cape Town	2	4	1	0	0	7
C8: private committee, Pretoria	0	0	1	2	1	4
TOTAL	3	4	2	3	5	17

Table 2.1 gives us a detailed review in terms of the professional background of my interviewees. Because of confidentiality issues, the last two tables (2.2 and 2.3) are less detailed in terms of professional categories. The terminologies used in these two tables will be employed also in the statistical tests, as summarized below:

- *Lay members, nurses and social workers*
- *Social scientists*, including sociologists, anthropologists and psychologists
- *Bioethicists and lawyers*
- *Bioscientists*, including natural scientists, pharmacists and statisticians
- *Physicians*

The following table presents further information about the committees studied.

Table 2.4 – Committees studied: 2011

Committee	Country	City[11]	Hosting institution	Members*	Number of meetings observed
1	Brazil	São Paulo	Public university	B	0
2	Brazil	São Paulo	Public hospital	A	2
3	Brazil	São Paulo	Public university	C	4
4	Brazil	Brasília	National commission	B	0
5	Brazil	Porto Alegre	Private hospital	A	0
6	South Africa	Cape Town	Public university	B	1
7	South Africa	Cape Town	Public university	B	3
8	South Africa	Pretoria	Private committee	A	1

* To preserve the committees' confidentiality, I am classifying them, in terms of size, into three groups: A – from 1 to 20 members; B – from 21 to 40 members; and C – 41 members or more

These committees represent different institutional situations, being based in public and private hospitals, universities, one private hospital and one national committee. In addition, committee 8 is organized as a private company, receiving direct fees for its reviewing tasks. As explained in the Chapter 1 – Introduction, this committee reviews research proposals to be conducted in South African private hospitals and practices, which generally do not have their own committees. There is another private committee in South Africa, also based in Pretoria.

As Table 2.4 above shows, 11 meetings were observed during my fieldwork (6 in Brazil and 5 in South Africa). Thus, it was possible to circumvent what Adler and Adler (1998) point to as the main limitations of observational techniques: the precarious generalizability of information and the lack of precision. My observations

[11] The geographical location of these cities in indicated in Map 1.1 and 1.2, page 28.

were made more generalizable because they involved five different committees, as well as different moments. In this way, my observations were provided with the remedies of time variation, which is recommended by Kidder (1981), and place variation, recommended by Lofland (1994). In addition, precision was obtained by combining the observations with another research method (interviews), as recommended by Adler and Adler (1998).

My purpose was not to intervene or transform these social contexts and, therefore, I stayed away from the characteristics that according to Kemmis and McTaggart (2003), define action research. On the contrary, in all cases I tried to assume discreet attitudes, never interfered in the committees' discussions, and tried to remain as unnoticed as possible. In committees 3, 6 and 7, these goals could be reached. In committee 3, for instance, the members sat around a very long table, while I took my seat in a separate chair; thus, I was actually sitting at many members' back, and covered from the view of many others more. In these three committees, I was then free to take detailed notes during the meeting. In committees 2 and 8, however, I was invited to share the table with the members. Then, I did not feel at ease to write long sentences and decided to take notes very sparingly, just writing down some words. After the meeting, I used these words to remember relevant points and take detailed notes.

Meetings proved a good opportunity to approach members and invite them for interviews. In committee 3, for instance, most members had become quite familiar with my presence after my third observation; thus I felt comfortable to approach them and propose interviews. This strategy was particularly useful for professionals who are represented in small numbers in committees, such as lawyers and lay members.

In spite of the relevant information gleaned from these observations, my analysis requires detailed discourses that cannot be voiced in a busy committee meeting. Thus, my main source of information had to be the individual conversation with members in the interviews. In the following section, I describe the qualitative analysis of these interviews, as well as the ancillary statistical tools I used.

2.4 CONDUCT OF INTERVIEWS

Due to cultural reasons, interviewing people was less complicated in my native country (Brazil) than in South Africa, a country I had never been to before. However, this difficulty was tempered by two circumstances. First, I had conducted many interviews with committee members and clinical research professionals before going to South Africa. Thus, I was very familiar with the issues and jargon pertaining to global trials. Second, even though my three-month stay did not allow me to have a deep understanding of the South-African culture, I did grasp some of its aspects, especially by interacting with people in non-research contexts and reading several newspapers.

All the interviews were recorded with permission from the interviewees. There was only one situation (in São Paulo) in which the interviewee did not allow the recording to be done, and then I took notes while talking to him. In average, interviews lasted 44 minutes and 33 seconds. The longest interview (in Cape Town) lasted 72 minutes, while the shortest one (in São Paulo) took only 14 minutes and 7 seconds. The interviews were semi-structured, with open questions explored according to the feedback received from the committee member. However, I tried to repeat some key questions in all interviews.[12] The structure used to guide my interviews is presented in Appendix 1.

While conducting the interviews, I tried not to influence the interviewees' responses by means of ideas and key words voiced in the questions. Therefore, I used, as it were, neutral (and sometimes even vague) questions, such as: "In your opinion, what is the main goal of clinical research?" or "Do you think there is any difference between academic research and the studies sponsored by the industry?" As my analysis developed, in the fieldwork, I was able to identify some key ideas and expressions fraught with ideological implications. These expressions (such as vulnerability, risks and benefits, methodology, exploitation, interests, among others) were carefully avoided in my questions. Thus, before using them, I waited for the word (or its description) to be spontaneously invoked by the interviewee.

[12] In the following chapters, when I quote parts of interviews, these questions will appear many times.

2.5 ANALYSIS OF INTERVIEWS

Four different softwares were used in the analysis of my interviews. Recordings were listened to with Media Player; the actual quotes were written down in Word; basic information of interviewees and committees was kept in a small database in Access; and an index of relevant issues addressed by interviewees was made by using Excel.

I listened to each interview at least three times, transcribing the most important parts, and translating the interviews conducted in Portuguese into English.[13] My main concern was not to identify personal and original claims. As I am interested in ideologies that are somehow normalized in society, I focused, rather, on claims that tend to be repeated and voiced by different interviewees in different contexts. Thus, it is necessary to introduce a concept that will be crucial throughout my text: the concept of *claim.*

By speaking of *claim*, I refer to verbal statements that appear in many interviews, though under different forms. It is, therefore, a sort of standardized idea, being voiced by different committee members in order to express views about clinical research. From the committee members' standpoint, *claims* seem to offer two advantages. On the one hand, they have their social history, being therefore full of meaning. On the other hand, they can be expressed in several ways, be it through sophisticated concepts or by means of ordinary language.

For example, during my fieldwork a very widespread *claim* (that is, a *claim* that was voiced by many committee members) was the idea that clinical research subjects must be provided with full and clear information about the study to be conducted. In the following quotes, we see two different ways in which this *claim* emerged in my interviews.

> "*And in your opinion, what is the main goal of clinical research?*
>
> [...] The most important thing (I'm saying it from my point of view), the most important thing [...] is the participation of patients, of research subjects, to see if they're conscious, responsible, if they understand what they're signing, if they receive

[13] Portuguese was the language used in the interviews conducted in Brazil. In South Africa, English was used.

all the information about the project, all the instructions... So I really pay attention to see whether the consent form will clarify the subjects' minds, so to say [...] So the language must be very clear, objective, a simple language, with no technical terms [...] That is why I ask for clarity... All the details. The more, the better."
(São Paulo/C3/Lay member/05-11)

"*And do you generally find problems in the [consent] form?*
That is rare because nowadays, as you know, the industry and the researchers have already learnt... There are any sorts of templates on the internet [...] The consent form ends up having to be very specific in terms of what is to be done with the patients, as well as the protections and safeguards to be offered, even though it is to say: 'We cannot guarantee that this new medication is better than your old medication but that is why we're proposing you to try it, because that will help us know if it is equally effective or not.' That must be absolutely clear [...] You must have written guarantees that what is being done, first, is aimed to improve, it is a study where, of course, you're being "used" (with quotation marks) in order to see if the new agent is good or bad, and that you can withdraw at any moment, and that you have rights to any kind of information. That must be clearly stated."
(São Paulo/C2/Physician/04-11)

This is the way I shall be quoting parts of interviews throughout my text. My questions and comments are quoted in italics. I tried not to cut sentences many times, even though this had to be done sometimes, because in oral discourses there are often repetitions. Moreover, cuts are necessary not to extend the text very much, in terms of word count. In order to protect my interviewees' confidentiality, I am using codes after each quote. This code expresses four elements of the interview: the city where the conversation happened; the committee number (as shown in Table 2.4); the inteviewee's professional background; and month and year of the interview. Thus, the following code:

(São Paulo/C2/Physician/04-11)

must be read in the following manner: the interview was conducted in São Paulo; the person is based in committee 2; he or she is a physician; and the interview happened in April 2011.

After having detected different types of *claims,* I tried to verify the ways in which claims are combined. It was possible to see that certain claims tend to appear in tandem. For example, the idea that full information must be imparted to patients is very frequently combined with the idea that patients must be let free to take autonomous decision pertaining to their participation in clinical trials. Therefore, particular combinations of claims lead to the formation of *discourses*, expressing particular *mentalities.* From Chapter 3, my task is to describe and interpret *discourses* and *mentalities.*

In my study, I could identify the existence of seven *mentalities*, which received the following names: *pragmatic, bioethical, communitarian, technical, analytical, healing,* and *critical.* The claim presented above (stressing the importance of full information) was found to be generally (but not exclusively) voiced by people who hold the *bioethical mentality.* The actual association between claims and *mentalities* derived from my historical and sociological analysis, as we shall see in the following chapters.

While analyzing the interviews, I realized that this kind of interpretation opens up some leeway for a quantitative analysis. The basic procedure is simple: each time a certain claim is voiced, a score is attributed to this claim and its respective *mentality.* However, it was necessary to take into account the emphasis with which claims are voiced. Depending on the emphasis, a particular score was attributed. I describe the different types of claims in the table below:

Table 2.5 – Types of claims and scores

Type of claim	Characteristic	Example	Score
Central	The main point made by the interviewee	"*When you're reviewing a protocol, what is your main concern?* Hm... It is... I suppose, in a sense, it is that the people will know... First of all, it is there is a sense of... that people will be informed about what is going on. So it is to know, myself, what they're doing, what the researcher wants to do, and to make sure that all that information will be available at a level of language that they [the subjects] understand [...]." (Cape Town/C7/Anthropologist/07-11) [Here, the idea of full information is the core of the interviewee's statement.]	3
Ancillary	A secondary point in the interviewee's speech. Often, the point emerges as an example to underpin the main statement.	"*Do you think that for those who don't have a medical background, reading a protocol can be somehow more difficult? Can there be further difficulties?* I think so. There are many technical terms that those who are not physicians will not understand [...] And then, I think, what can they analyze, basically? The ethical part. Would I do... Would I agree to participate in this study? [...] And something that is very important is the informed consent form. If that person who is not a physician reads the form and doesn't understand it because there are too many technical terms, he or she will surely question that [...]." (São Paulo/C1/Physician/04-11) [Here, the idea of full information appears as a secondary point.]	2
Confirmatory	The interviewee quotes a generally accepted idea, agreeing with it	"*And do you have a different view about the research that is sponsored by the industry?* I told you, I know studies that say that. Trials sponsored by the industry tend to have much more positive results for that product than studies done by universities without funding from the industry." (São Paulo/C3/Social scientist/05-11) [The interviewee agrees with the studies she refers to.]	2

Type of claim	Characteristic	Example	Score
Indirect	The point is only suggested, but not explicitly stated, by the interviewee	"I am very proud of being in the committee, even though I consider this work to be somewhat dry, you know, because, as I told you before, in the analysis of a project I don't dare to invade the questions that are specific to the medical specialty, and I stick only to legal issues, legal consequences, and especially the issue of informed consent, in order to see if everything is respected, if the rights are respected or not." (Porto Alegre/C5/Lawyer/05-11) [The idea of full information to participants is indirectly cited, when he speaks of informed consent.]	1
Repetitive	The interviewee agrees with a statement presented in my question	"*Do you consider it [participation in the committee] as work or your work is as nurse?* No, I don't consider it as work [...] *If it is not work, how could we consider it?* I think it is a scientific contribution, you know, a contribution [...] *A contribution to science...* Yes, yes, surely [...]" (São Paulo/C2/Nurse/04-11) [The interviewee clearly agrees with my suggestion that her work is a contribution to science.]	1

Confirmatory claims were sparingly voiced by my interviewees. Repetitive claims were also very rare, for I strived to let claims emerge spontaneously. I always tried to ask the type of question that Krueger (1994, p. 57) described as "open-ended questions," which leads to a reply that "[...] reveals what is on the interviewee's mind as opposed to what the interviewer suspects is on the interviewee's mind." The fact that repetitive claims were given a small score (1 as opposed to 3 for central claims) is a quantitative compensation for the fact that in these rare cases, the interviewee, instead of voicing a spontaneous claim, simply confirms what my intervention suggests.

Thus, for each claim, I had a classification (in terms of *mentalities*) and a score (in terms of types of claims). I added up all the scores, in order to obtain the overall score of the interview. I grouped the scores voiced according to their *mentality* (*pragmatic, bioethical, communitarian,* and so on). Then, considering the overall score,

I verified the percentage obtained by each *mentality.* Thus, after analyzing one interview, I had something like:

“Overal score: 90
Bioethical mentality: 12% (or 0.12)
Technical mentality: 7% (or 0.07) ...”

And so on. The following quote shows one answer given by one of my interviewees. The answer is broken into different parts, in order to exemplify how I analyzed different sections of interviews:

Table 2.6 – Analyzing discourses: an example

Interview	Analysis	Justification
"*In your opinion, what is the main goal of clinical research?* Probably, it would be to do the trials in a safe way	Protecting bodies Communitarian mentality Indirect claim Score = 1	The interviewee only suggests the idea that patients must be protected
and to do the trials in an ethically sound manner, with the *informed* consent of the participants. For me that is very important. If people don't know the things that can go wrong with the trial, how can that be informed consent? So they need to be told: 'This is the first time we're trying it on humans,' for instance. 'We've done it in animals but now we're doing it in humans. These were the things that we found as side effects or whatever in the animal population.' So I think people should know those kinds of things. And then, also... What was the question again? *What is the main goal of clinical research. The main target.* The main goal. The main target. I...	Full information Bioethical mentality Central claim Score = 3	This is the main point made by the interviewee in this section
As I said, trials should be done in a safe way.	Protecting of bodies Communitarian mentality Reiteration Score = 0	As the idea had been advanced before, no score is attributed here.
I know that it is unpredictable how drugs would... their effect on the body if they've been studied for the first time, but, still,	Uncertain research Communitarian mentality Ancillary claim Score = 2	The interviewee advances the *communitarian* idea according to which there is always a certain degree of uncertainty in research. The claim is, however, a secondary point to her main statement.
the people doing the trial should try and limit the effects or side effects (as much as they can) of the drugs that they're testing or... As much as knowledge they have should into making it fairly safe for people.	Protecting of bodies Communitarian mentality Reiteration Score = 0	In a different way, the interviewee repeats the claim that research subjects should be protected against harms in trials.
And then, also, I would like people to inform patients exactly what it is that they're doing."	Full information Bioethical mentality Reiteration Score = 0	She finishes by reiterating her main argument.

Thus, I am not attributing scores when the idea is repeated within the same section. A new section begins when I ask a different question, changing the topic of conversation. In this way, one same claim can, and frequently was, repeated in

different sections of the whole interview, receiving many points. The final quantitative outcome of the section quoted above is:

Overal score: 6
Bioetical mentality: 0.50 (50% of the overall score 3)
Communitarian mentality: 0.50

In appendix 3, I present the full transcript of one of my interviews, as well as its quantitative analysis.

These figures were used in order to perform some statistical tests, as I explain in the following section.

2.6 STATISTICAL TOOLS

Quantitative discourse analysis has been used in some social science studies. Different approaches have been chosen, such as counting some words which are value-laden (Steger and Wilson, 2012), classifying preferences with ideological rating scales (Kalt and Zupan, 1990), running statistical analysis based on the use of discourse markers (like "you know" or "look") (Czerwionka, 2012), organizing quantitative rankings of ideas or statements (Hobson and Niemeyer, 2011, Rinne and Fairweather, 2012), or measuring the occurrence of certain types of talks (like questions, advice or affirmations) (Li et al., 2007).

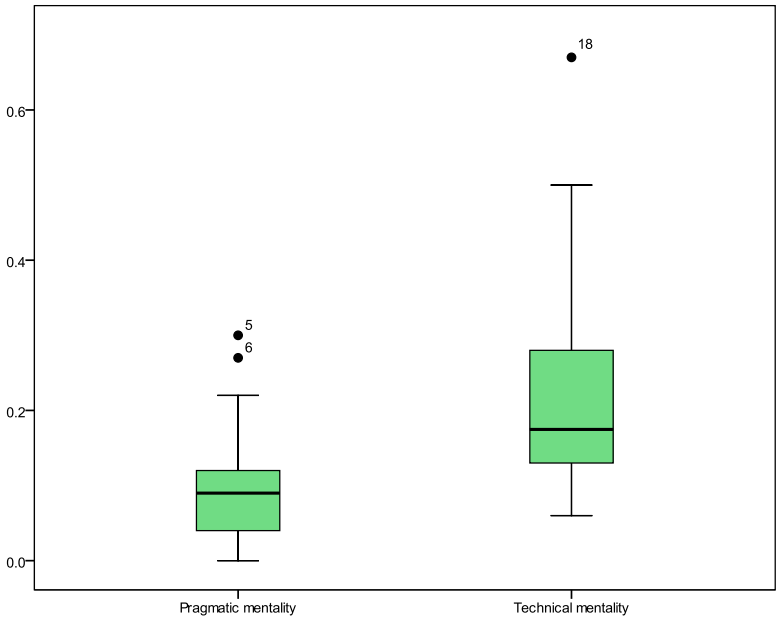
Drawing on Habermas' theory, Ma (2012) defends the viability of mixed methods claiming that quantitative analyses can help grasp aspects that may not be completely unveiled in qualitative analyses. "Since conditions such as money and power often escape the explicit awareness of actors and thus may not be explicated by hermeneutic or interpretivist methods alone, analytical methods such as statistical analyses of large-scale data may be demanded for generating a 'big picture' of the phenomenon" (Ma, 2012, p. 1865).

Statistics appears as an ancillary tool in my thesis. This is a qualitative study and the fieldwork was conducted accordingly. However, while analyzing my interviews, it

was seen that some *ad-hoc* statistical instruments could be used to further support my interpretation. Moreover, my quantitative analyses were not permitted to hinder the complexity of the qualitative interpretation. It is possible to say that in applying some quantitative analyses, I adopted the stance described by Creswell and Clark (2007) as multiple paradigms, for I did not oblige myself to circumvent contradictions and paradoxes for the sake of numerical coherence. In addition, I did not follow the patterns proposed in the aforementioned or other mixed methodologies, because the particular features of my interpretation asked for an equally particular quantitative design.

By using SPSS 17, I utilized some descriptive and analytical methods to display, and perform calculations with, my data. The first resource I used is the boxplot, with which I show the distribution of the ratios I obtained for different *mentalities.* For example, the following boxplots (I am calling them *discourse boxplots*) show the ratios obtained for the *pragmatic* and *technical mentalities* in all my interviews.

Figure 2.1 – Discourse boxplots: pragmatic and technical mentalities



These boxplots show that the proportion of technical claims voiced by my interviewees was bigger than the proportion of pragmatic claims. The lowest

proportion of pragmatic claims was of 0, whereas the lowest proportion of technical claims accounted for 0.06. The median score of pragmatic claims was of 0.09, whereas the median score of technical claims was of 0.17.

My analyses of interviews revealed that I could not have a very accurate idea about people's discourses for interview recordings lasting less than 30 minutes. Thus, in order not to distort my statistical analyses, I divided my 42 interviews into two groups:

- Weak interviews: lasting less than 30 minutes
  8 cases
- Strong interviews: lasting 30 minutes or more
  34 cases

In order to perform calculations and build graphics (as explained below), I used only data from strong interviews. Thus, weak interviews were used only as sources of examples of *claims*.

By running histograms (which are presented in Appendix 4), I found out that part of my data is non-normally distributed. When this occurred, non-parametric tests were used; otherwise, I performed parametric tests, according to what is recommended (Leech et al., 2008, Kinner and Gray, 2004).

We shall see that in some situations, I divided my interviewees into groups (professional groups, for example). As each group is composed by a small number of interviewees, significant differences do not always appear. Thus, in most cases, we can only show some tendencies, which can nevertheless complement the main qualitative analysis. However, there were cases in which it was possible to assess tendencies quantitatively. I used the following tests:

PARAMETRIC DATA

- To compare pairs of groups, I used the Paired-samples T test
- To compare three groups or more, the One-Way ANOVA test was performed

NON-PARAMETRIC DATA

- To compare two related groups, I used the Wilcoxon test, always quoting exact values.

  Justification: this is the classic test for comparing two groups when non-parametric data are analyzed. Exact values are specially suitable when one works with small samples
- To compare three or more related groups, I used the Friedman test

  Justification: this is the recommended test for more than two groups when data are non-normally distributed. The Kendall's tau-b test could be used, but this test is more suitable to compare trends, which is not the case here
- To compare two independent groups, the Mann-Whitney test was performed, and exact values quoted

  Justification: this test is suitable for two groups with non-normally distributed data
- To compare three or more independent groups, the Kruskal-Wallis test was performed, and exact values quoted

  Justification: This is the appropriate test for nonparametric data and more than two samples
- To correlate variables, I used the Spearman correlation

  Justification: as I am working with small samples, the alternative test (Pearson correlation) could prove too conservative, underestimating some correlations (Leech et al., 2008). Thus, as I explain in the following chapters, some variables were transformed into ranks, so that the Spearman correlation could be performed

One descriptive tool, which I created for the purposes of this study, is what I am calling *discourse graphic.* As explained before, each *mentality* has some *claims* that are associated to it. Thus, I divided each mentality in sub-groups of *claims,* obtaining detailed results. For example, after having analyzed one interview, I had the following type of data:

“Overal score: 109

Pragmatic mentality: 0.22 (or 22%)

Claim PRAG1: 0.11

Claim PRAG2: 0.03

Claim PRAG3: 0.08

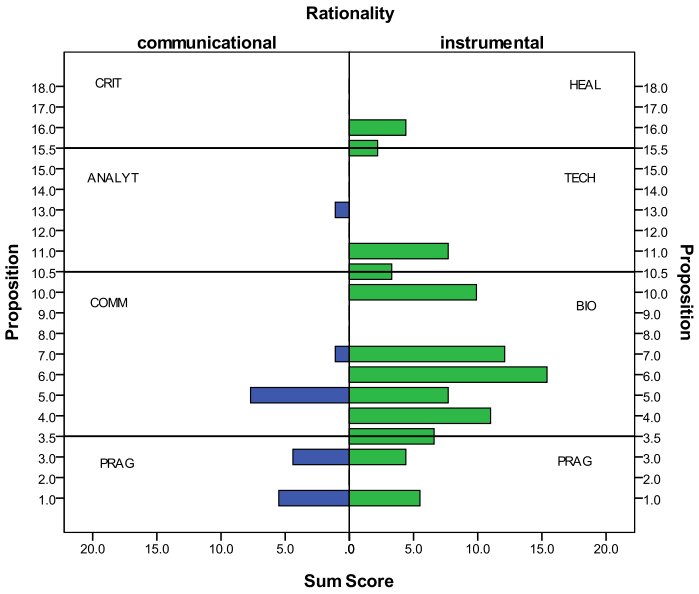
Bioethical mentality: 0.09 (or 9%)

Claim BIO7: 0.01% ...”

And so on. Therefore, the ratios of different *mentalities* were divided into sub-groups of claims. As a result, the overall discourse voiced by one interviewee could be represented with a graphic, as the following example shows.

Figure 2.2 – Discourse graphic n. 24

(São Paulo/C2/Nurse/04-11)



The graphic is composed by two main areas: the *communicational rationality* (on the left) and the *instrumental rationality* (on the right). As explained before, this division was proposed by German sociologist Jürgen Habermas. In addition, there are eight sub-areas corresponding to the *mentalities* I identified in my study. The *pragmatic mentality* occupies two sub-areas because, as we shall see, it belongs to both the *communicational* and the *instrumental rationalities.*

Each group of claims is represented by one bar. In the example above, we can classify this discourse as *bioethical*, for two reasons. First, the majority of claims voiced fall within the field of *bioethical mentality.* Second, bars are longer in this sub-area, meaning that bioethical claims took the biggest proportions in the interviewee's overall score. As we can see, the most important group of claims is BIO6 (15.4%). This group of claim stresses the importance of national and international guidelines in ethical reviews undertaken by committee members.[14]

A full list of claims voiced by my interviewees and represented in discourse graphics, as well as their classification according to mentalities, can be found in

From the next chapter, I present my interpretation of global trials, *rationalities* and *mentalities.* Before beginning, however, it is important to remember that when Habermas speaks of *rationality*, he is not referring to the ways in which individuals think. Neither does the present thesis adopt such individualistic stance. Committee members' particular psychological processes are not the target of my interpretation. Here, individuals' claims are rather means to understand broad ideological processes that have been running in this period of advanced globalization.

[14] This is discourse graphic number 24. The numbers of discourse graphics have no meaning. They simply represent the order in which data was typed into my SPSS database.

Chapter 3 – Background knowledge: the pragmatic mentality

In this chapter, we begin to analyse the information collected in my fieldwork. We shall focus on a basic, widespread approach to clinical research. Initially, it is necessary give some brief clarification.

As explained in the previous chapter, I draw on Habermas' (1981/1987, 1996) theory of communicative action. In my study, the concept of *rationality* has to undergo an adaptation in order to be applied to the empirical examples I focus on. During my fieldwork, by conducting interviews and observing some ethics committee meetings, I could identify two main patterns with which people frame the globalization of clinical trials. Exploring the characteristics of these two ideological stances, I concluded that they can be seen in the light of Habermas' concepts. Therefore, I arrived at the following description.

- In ethics committees, *instrumental rationality* is expressed whenever committee members deal with research projects by handling principles and concepts with which an objective, almost universal assessment of research proposals is sought. Committee members would be supposed to verify whether particular studies fit into established regulatory, moral and scientific moulds (such as bureaucratic forms, randomization or ethical principles), which are then considered as the most relevant aspect of an ethical review

- Committee members express the *communicative rationality* whenever they foreground financial, social or scientific particularities of research projects. In this way, committee members would be supposed to take into account specific aspects of studies (such as the study population, the study's budget, research

sites' infrastructures, national needs, among others) in order to verify whether research is feasible and necessary or not

It is important to identify and study these two stances toward clinical trials because they provide the underpinnings of political debates taking place in South Africa and Brazil, but other countries as well. Thus, the present study is in tune with the theory of communicative action's tenets, in the sense that I do not aim to undertake psychological analyses but to grasp social and political patterns.

Nevertheless, my fieldwork revealed that it is not enough to talk about *rationalities.* When dealing with social debates, we are in need of two other concepts: *discourses* and *mentalities.* After discussing these concepts in the following section, we move on to analyzing the features of the pragmatic approach to clinical trials, focusing on its characteristics, sources and implications.

3.1 ETHICS COMMITTEES, DISCOURSES, AND MENTALITIES

In a sense, committee members are decision-makers. However, it is important to verify how they can (or must) take decisions. Even though ethics committees are frequently seen as bodies that take collective decisions, this is not always the case. Depending on the committee's organization, most projects are reviewed by only one person. Of eight committees I studied, only two (committees 2 and 4)[15] do not employ the so-called fast-track system. In this process, which is reserved for so called "low-risk" projects, proposals are assessed by only one committee member, whose final decision is not discussed in the meeting. Clinical trials proposed by pharma companies never go through fast-track assessments. However, the whole protocol submitted by companies is generally read by only two reviewers, and their judgements are subsequently discussed in the meeting. "High-risk" projects are read by two reviewers in all the committees I studied, excepting committee 8, in which all the members are sent the whole protocol.[16] However, the members of committee 8 do not actually read projects as a whole, focusing instead on topics pertaining to their particular expertise

[15] Information about each committee is presented in Chapter 2, Table 2.4, page 50.
[16] This is a professional committee, in which members are remunerated for their work.

areas. In committees 6 and 7, all the members are sent the summary of all protocols, as well as consent forms, some days before the meeting.[17]

Of course, this organization has to do with the voluntary nature of the committee members' work. If all members were supposed to assess all the protocols received by the committee, their work should be done on a professional (and remunerated) basis. Therefore, most research proposals end up being fully assessed by only two reviewers, while the other committee members only have access to either summaries or verbal descriptions made by colleagues in the meeting. As a consequence, many committee members end up looking at the review (that is, the actual reading of research protocols) as their main responsibility.

> "*Do you think that the meeting is the most important part of the committee's work?*[18]
> No. No, the reviewers must be well-prepared. So when they come to the meeting, that is just presenting the review. If the reviewer comes in unprepared and one of the committee members pick up one of the ethical issues and then say: 'Well, how do they address this? Because this is an ethical issue that needs to be discussed in detail in the protocol itself.' And if the reviewer looks at page two and tries to find it and etcetera, then it is going to waste a lot of time [...] So that preparation that happens before the time is very important."
> (Cape Town/C6/Physician/08-11)

> "*Would you say that the meeting is the most important moment in the work in the committee?*
> No. Not at all. I think the meeting is a silly thing. The meeting is important when you have an important issue to discuss, that is true. But when you don't have it, it is not [...] In the meeting you attended, we discussed protocols, spelling mistakes, mistakes... These are issues for people who don't have anything serious to discuss, effectively. When there is an issue... 'Placebo in victims of violence versus anti-depressives.' This is a serious discussion [...]
> *But generally, these discussions don't happen in the meeting.*
> They happen when there is a project, Edison, when there is a project like that. It doesn't happen as a general topic for the meeting [...]

[17] By observing the meetings of these two committees, I realized that most members do read summaries and consent forms prior to the meeting.
[18] When I quote parts of interviews, my questions and comments are presented in italics.

If the meeting isn't the main moment, what would be the main moment?

Oh, I think it is the reading."

(São Paulo/C2/Physician/04-11)

The two quotes above do not express deviant stances. Actually, my fieldwork led to a quite surprising finding: of 27 committee members to whom this question was asked, 14 people considered the meeting as an ancillary moment in their set of duties. Therefore, it is certainly possible to say that there is a decisive individual content to ethics committees' operations. Even though some research projects can be considered as relatively simple,[19] committee members are often confronted by innovative research techniques that may trigger doubts and dilemmas, asking for a decision that is often taken individually and has to be issued in terms of *yes* (accepting the research proposal), *no* (refusing it) or *maybe* (asking for corrections and or clarifications). As such decisions must be taken on a regular basis, committee members end up formulating their own concepts and ways of assessing protocols. As Habermas (1993, p. 3) explains: "In complex cases decision-making strategies themselves must be developed; then reason seeks reassurance concerning its own procedures by becoming reflective [...]."

Here, we come to a central point: even though people are asked to develop "strategies" to cope with dilemmas and take decisions, such strategies do not always result from original, personal formulations. As we shall see throughout my exposition, people may, and really do, mobilize patterns of ideologies which are socially available in order to tackle problems presented by everyday life. *Rationalities* (namely, the *instrumental* and *communicational rationalities*) are the basic patterns on which people rely. Thus, for instance, when assessing a clinical protocol, one committee member identifies some issues that can be seen either in the light of general principles (*instrumental rationality*) or from the point of view of contextual factors (*communicative rationality*).

However, my research enabled me to realize that at an individual level, *rationalities* are too broad and complex to be fully assimilated and handled. Instead, it

[19] Indeed, the majority of studies reviewed by ethics committees are students' projects that come to be classified as "low-risk studies" and go through the "fast-track" system. In South Africa, for instance, I attended a committee meeting in which, out of 30 proposals discussed, only 5 were clinical trials submitted by pharma companies.

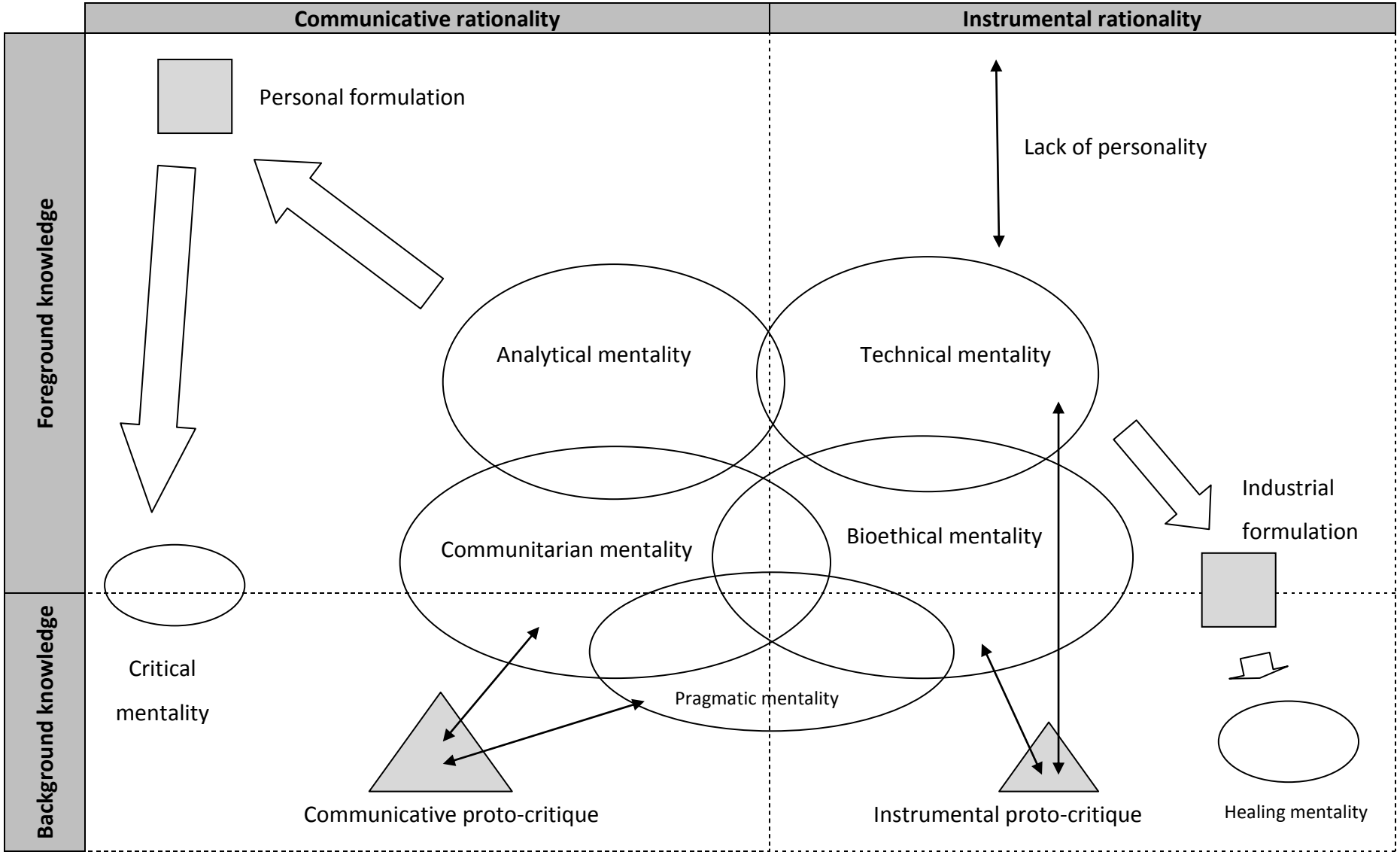
is possible to surprise people mobilizing specks of *rationalities,* which seem to be more meaningful for particular individuals. Therefore, I came to identify what I propose to call *mentalities,* which are the ideological components of the two main *rationalities.*

When talking about *mentalities*, I am not referring to psychological or psychiatric phenomena. The term comes from German sociologist Georg Simmel (1903/1950), who claimed, in a classic text, that life in big cities implies the assimilation of a particular "mental life." With this expression, Simmel referred to a mindset developed by the inhabitants of big cities in order to cope with the numerous stimuli generated by the urban environment. Urban inhabitants can therefore formulate quick responses without getting paralyzed by frequent and complex calculations. Exactly as Simmel did, I speak of *mentalities* to describe the ideological (or cultural) resources with which people process and solve dilemmas proposed by everyday life. In my study on ethics committees, I came to identify the following seven *mentalities.*

1. The p*ragmatic mentality* focuses on practical aspects of clinical protocols, such as financial interests of companies and institutional interests of researchers
2. The *bioethical mentality* operates with general principles in order to identify aspects through which research projects can be compared and commensurated
3. The *technical mentality* stresses scientific aspects of research, looking at research projects from the viewpoint of the generation of knowledge
4. The *healing approach* considers clinical research as an endless effort through which new therapies and medicines are generated
5. The *communitarian mentality* focuses on local and contextual aspects, being especially concerned with socially marginalized groups
6. The *analytical mentality* delves into the scientific intricacies of research projects, considering clinical research as part of a broad social structure
7. The *critical mentality* points out insurmountable frailties in the system of clinical research

As we shall see later in this chapter, *pragmatic* concerns are shared by the *instrumental* and *communicative rationalities.* Thus, it is possible to present the following scheme, which will guide us in our trajectory:

Figure 3.1 – Rationalities and mentalities



Depending on aspects of individual biographies, mentalities appear not only as ideological options but as the only means available in order to cope with everyday concerns. Therefore, people do not always enjoy high degrees of ideological flexibility and "[…] the question arises of how autonomous the public is when it takes a position on an issue […]" (Habermas, 1996, p. 375). Depending on the issue at stake, one's ideological autonomy may only consist in the choice between different *mentalities* in order to voice meaningful claims.

On this point, the idea of concern acquires a decisive weight. Social actors need to handle rationalities and mentalities because society is always imposing concerns. As Arendt (1958/1998, p. 57-58) explains, social reality is not defined by biological similarities between people but "[...] by the fact that, differences of position and the resulting variety of perspectives notwithstanding, everybody is always concerned with the same object." Therefore, the proliferation of issues perceived as deserving attention and reflection reinforces mentalities, which emerge as ways to respond to these concerns.

Globalization tends to endow mentalities with international reach. In the field of clinical research, the globalization of studies, procedures and economic schemes obliges different countries to cope with similar issues. For those people who tend to be more aware of international clinical protocols (such as ethics committee members), a similar range of concerns arise in different contexts. Therefore, each mentality is likely to undergo a more or less important development in different cities, regions and countries. These processes tend to acquire momentum in our contemporary period, when people are used to the idea of world history. According to Arendt (1958/1998, p. 47), this idea was greatly reinforced by the French and American Revolutions, when people trumpeted the existence of "[...] events which would concern all men *qua* men, no matter where they lived, what their circumstances were, or what nationality they possessed [...]."

Therefore, mentalities are the product of a twofold phenomenon. On the one hand, they come to cross over national frontiers and emerge in different contexts, defining homogeneizing trends. On the other, there are fragmenting trends, because mentalities draw on differences between ways of living and ideological biographies,

which make people choose certain *mental* resources instead of others. As Durkheim (1932) noted, the division of social labour, as well as the complexification of societies, gradually undermines the homogeneous ideological pattern that prevailed in ancient societies.

Rationalities and mentalities are mobilized not only to deal with concerns but also to identify those concerns themselves. For instance, the financial interests of pharma companies are regarded as major troubles from the viewpoint of the *pragmatic* and *communitarian mentalities* but tend to be considered as minor points by people favouring the *technical* approach. In this sense, *mentalities* influence the ideological organization of social life. "For to organize means to organize some things *in* and other things *out*" (Douglas and Wildavsky, 1982, p. 8).

Habermas (1996) points out that communicative actions are expressed not only by means of verbal messages. Actually, every human action carries a certain message that can be understood by other social actors. Nevertheless, verbal messages are certainly a privileged way to convey mentalities, especially in the framework of my study, in which interviews were used as a basic research instrument. These interviews allowed me to verify how people select *claims*[20] from different mentalities in order to build up a *discourse.* Therefore, *discourses* can be defined as what results from the use that people make of *claims* and *mentalities*. They are personal constructions of meaning, based on what is available in the *mental life* of a social group.

To be sure, in some cases the ideological combinations made by individuals, in their discourses, turn out to be very original or even curious. This is why the identification and comprehension of mentalities is not a straightforward task. My research process was marked by the effort to solve a difficult puzzle of claims. Before my fieldwork, I could identify the approaches composing the instrumental rationality, but I could not go beyond this initial step. In the fieldwork, by interviewing people, some claims seemed to escape the rationales of the *pragmatic, bioethical, technical* and *healing mentalities.* By the middle of my fieldwork in Brazil, I realized that I was in fact dealing with other mentalities, expressing a parallel (*communicative*) rationality. After the fieldwork, going back to the notes taken at the beginning of my PhD, I saw that some claims had been wrongly classified. However, the identification of the

[20] On the concept of *claim*, see Chapter 2, section 2.5.

pragmatic mentality has always been quite straightforward, which is due to its simplicity and immediacy.

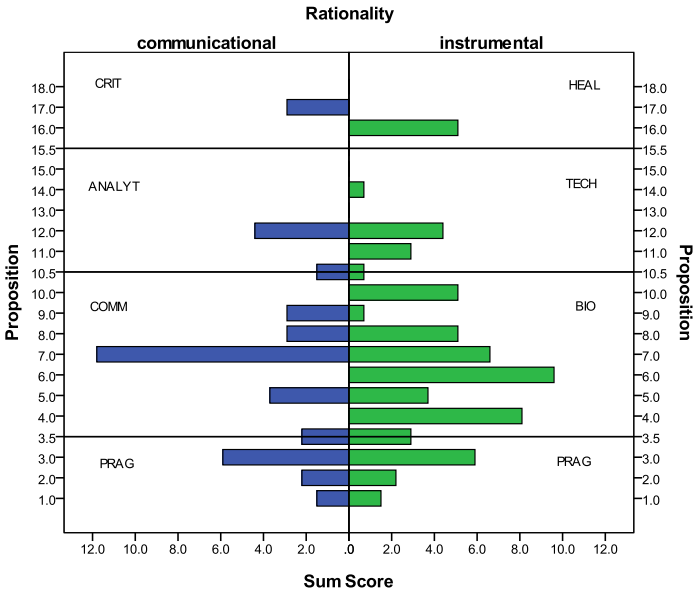
3.2 THE PRAGMATIC MENTALITY

O'Reilly and colleagues (2009) argued that "ethics" is produced by means of the ethics committees' work. Even though this argument can be accepted, it is important to underline that different committee members produce different accounts of ethics (or different *mentalities*).

As it was shown in Figure 3.1 (page 71), the *pragmatic mentality* underpins the whole mental life, being shared by the instrumental and communicative rationalities. It is a sort of driving force for all the other mentalities, which emerge as responses to the mental challenges proposed by the pragmatic mentality. With a *discourse graphic,*[21] a visual description of the role played by the pragmatic approach can be made.

Figure 3.2 – Discourse graphic n. 4

(São Paulo/C1/Physician/04-11)



[21] The construction of discourse graphics is explained in the Methodology chapter.

The discourse voiced by this interviewee (a physician) is dominated by bioethical claims and complemented by some technical and healing claims. The interviewee also voiced all possible pragmatic claims. Thus, the structure of this discourse is firmly underpinned by the *pragmatic mentality'*s basic assumptions.

In spite of this pivotal position, the pragmatic mentality is actually composed by simple notions and claims. Nevertheless, it is certainly worth studying, for in the framework of sociological/cultural analysis, complexity does not always signify relevance. As Geertz argued, there is much interest in studying notions that are considered as self-evident, taken-for-granted ideas by a certain social group. The study of common-sense notions also helps us understand "how culture is jointed and put together" (Geertz, 1983, p. 93). In Habermas' terms, we are referring here to *background knowledge,* that is, a set of fundamental assumptions largely shared in a social group, constituting binding notions.

> "From the very start, communicative acts are located within the horizon of shared, unproblematic beliefs; at the same time, they are nourished by these resources of the *always already familiar*. The constant upset of disappointment and contradiction, contingency and critique in everyday life crashes against a sprawling, deeply set, and unshakable rock of background assumptions, loyalties, and skills" (Habermas, 1996, p. 22).

In clinical research, these basic, simple, common-sense, unshakable assumptions are concentrated in the pragmatic mentality. The following sections are aimed to analyze its main features.

3.2.1 Clinical research and financial interests

According to Geertz (1983, p. 76), common sense is "[...] historically constructed and [...] subjected to historically defined standards of judgement." In other words, the ideological contents of *background knowledge* vary according to historical periods. Nowadays, in the field of clinical research, there is a notion that

imposes itself and is quickly accepted even by those who do not have access to precise figures: the universe of clinical trials has been largely dominated by multinational companies.

The idea that clinical research has been subordinated to commercial rationales is reinforced by the recognition that over the last years, companies have been responsible for the actual design of clinical studies whereas physicians have become ancillary players. Hence, the idea that "[...] in the context of clinical trials, it is the pharmaceutical companies with the scientific expertise dictating tasks to physicians" (Fisher, 2009, p. 233 note 44). As one of my interviewees put it:

> "[...] often GPs become a sort of handmaiden of the pharmaceutical companies because they're just, you know, handing on medications rather than doctoring [...] Ten years ago we had a lot more original research in the committee than we do today. And a lot of money might be coming in from the pharmaceutical research but it doesn't always... but it doesn't go to the sort of broader university context. It tends to go to researchers who are involved with the pharmaceutical company. It is very profitable for them to do it, but it doesn't necessarily involve research expertise and competence within the faculty."
> (Cape Town/C7/Social scientist/07-11)

In the face of such assumptions, an awkward contradiction emerges. On the one hand, clinical trials are indirectly associated with health care, which is thought of as an altruistic service. On the other hand, it is known that companies are seeking private interests and their activities, therefore, would be at odds with altruistic purposes. Even though people can concede that in certain aspects, companies are helping to make important discoveries, there remains the background assumption of essential financial motivations.

> "*By listening to you, I had the impression that from your point of view, clinical trials sponsored by the industry don't have any worth from the point of view of science. Is that correct?*

[Taking breath.] No, that is not strictly true [...] Coming back to my field (it is biological trials), they taught us an awful lot about the workings of certain kinds of inflammatory arthritis. So they have contributed from that point of view, but that is not their main aim. So please don't get me wrong. The main aim of these trials, I said before, is to sell their product.

Okay, so the scientific...

The scientific aspect is there but it is secondary."

(Cape Town/C6/Physician/08-11)

Thus, the pragmatic mentality is based on the assumption that there are financial interests underpinning the clinical trials' universe. Before moving on to exploring other aspects of this approach, we shall focus on some ideological sources of the pragmatic mentality.

3.2.2 Ideological sources

During the conduct of my PhD, I developed a sort of parallel, informal study. Sometimes, by revealing to friends and acquaintances that I was studying clinical trials, I witnessed interesting reactions. I verified that for many people, clinical trials are quickly associated with problematic studies, exploitation and huge financial interests. Even though these observations are not as accurate and systematic as my interviews, they certainly enabled me to have some contact with the *background knowledge.*

Over the last decades, analysts and the media have focused on clinical trials and circulated some basic facts and stories through which people have become aware of big shifts in the world of clinical research. As a summary, we can point to the following aspects:

- Clinical studies used to be carried out and funded by state institutions but have subsequently been dominated by multinational pharmaceutical companies (Epstein, 2007, Angell, 2005, Busfield, 2006, Bodenheimer, 2000, Petryna, 2009, Seruga et al., 2010, Fisher, 2009)

- The number of multicentre, international clinical trials has been growing steadily since the 1980s (Petryna, 2006, Epstein, 2007, Fisher, 2009)
- Due to business secrecies, pharma companies prefer not to disclose much information, preventing, for instance, the creation of comprehensive registries of trials being carried out worldwide (Petryna, 2009, Fisher, 2009)
- A plethora of companies have been created whose goal is to help pharma companies to conduct clinical trials in a more financially efficient way (Petryna, 2009). These new actors involve, among others: "[...] private practices, dedicated research centers, site management organizations (SMOs), contract research organizations (CROs), for-profit, commercial institutional review boards (IRBs), central patient recruitment companies, and clinical trials advertising agencies" (Fisher, 2009, p. 5)
- Among these new economic actors, Contract Research Organizations have proved especially aggressive in terms of results and financial efficiency (Mirowski and Van Horn, 2005, Fisher, 2009, Petryna, 2009)
- Another important new actor is the company specialized in finding and recruiting subjects for clinical trials (Anderson, 2003, Epstein, 2007, Mirowski and Van Horn, 2005, Fisher, 2009)
- Many partnerships involving pharma companies, CROs, researchers and state institutions have been established in order to develop clinical trials (Bodenheimer, 2000). "So it was just part of the new climate to do clinical trials pretty much the way the pharmaceutical industry wanted them done" (Angell, 2005, p. 102)
- A big proportion of medicines approved by regulatory agencies does not really amount to big scientific and therapeutic advances (Busfield, 2006, Abraham, 2009, Angell, 2005, Petryna, 2009), being instead aimed to explore market niches (Fisher, 2009, Petryna, 2009)
- There has been some evidence of strong relationships between regulatory agencies and pharma companies (Abraham, 2009, McGoey and Jackson, 2009, Busfield, 2006)
- Companies are striving to speed up the recruitment process, in an attempt to minimize delays and maximize profits (Epstein, 2007)

The globalization of trials itself can be included into this list, insofar as it has also been motivated by economic considerations. It is really hard to separate the conduct of global trials from the operations of multinational companies.

From these observations, one derives the *pragmatic* idea that the financial interests of pharma companies and CROs are somehow distorting the universe of clinical research. From this viewpoint, clinical studies have turned into mere tools to protect business privileges, as stressed by Busfield (2006, p. 307): "[…] since another company may be working on a competitor product and seeking to establish its superiority, the first may need to engage in further defensive testing."

> "*Do you think there are fundamental differences between an academic study and a trial sponsored by the industry?*
> [...] I think the academic research is more honest than the one sponsored by the industry, 'cause the industry's got an ulterior motive: to sell their products [...] Especially in the drug trials, you get so lot of comparative trials, comparative trials, it is comparing and comparing... But there is a good... This drug is good. Why waste... Why must now we have another protocol? Why do we need another drug which is, essentially, absolutely equal to the other one? It is the same... It is the same ingredients and everything [...] In the drug companies, there is a lot of comparisons [...]
> *And why?*
> Because they want to have a new drug that they can put on the market and it is business. It is business [...]."
> (Cape Town/C7/Lay member/08-11)

To be sure, the public is not aware of all the details of clinical trials. However, some data and stories do come to be largely circulated, especially by the media. In this way, many people end up reflecting at least on some aspects of clinical trials. These considerations can go beyond a basic level whenever clinical research and pharmaceuticals suddenly become a big national issue. Here, South Africa provides us with an instructive example.

In 1997, the South African government passed a law aimed to facilitate the access of people infected with HIV to anti-retroviral medicines. Measures included a mechanism of parallel imports, so that the country could circumvent patents and buy cheap generics. In the following year, 39 large pharma companies opened a lawsuit against the South African government, claiming that their intellectual property rights had been violated. In 2001, after much criticism against those companies and large publicity both in South Africa and internationally, the companies withdrew their case (Shah, 2006). In South Africa, the story continues to be recalled whenever pharmaceutical production is at stake. For instance, I interviewed a committee member who also works for the Medicines Control Council (MCC), the South African regulatory agency.

> "*[...] I suppose it must be difficult to reject a protocol from Pfizer, for example, from the big...*
>
> It doesn't matter how big the company is. We've been challenged; we've been taken to court. We won some cases, we lost some cases, we've had appeals... At the MCC [...] I don't know whether ethics committees have been challenged but in the MCC, we have been challenged."

Regardless of the amount of publicity that these stories manage to acquire, they always contribute to somehow shape the *background knowledge.* Hence the cautious (or unfriendly) reactions I got from some friends after mentioning my PhD study on global trials. To be sure, information about clinical research seldom go beyond the level of superficiality, but this is precisely the point to be made here: *background knowledge* is powerful because its contents can be easily assimilated by most people. To use Geertz's (1983, p. 91) concepts again, we are dealing with common-sense notions endowed with "accessibleness": "[...] there are really no acknowledged specialists in common sense [...] Being common, common sense is open to all, the general property of at least, as we would put it, all solid citizens."

This is what defines the force of the pragmatic mentality. It draws on direct, immediate observations of the world, spawning basic notions that are shared by almost everybody and making it possible for people to be focused on the same issues

and engage in conversations about them. For ethics committee members, the pragmatic mentality plays a decisive role. Under the sway of its stimuli, members become *concerned* about the same phenomena and are invited to subscribe to *mental* formulations that are, at the same time, individual (because there are personal ways to deal with pragmatic concerns) and collective (because the committee works as a group and research proposals need to be collectively discussed at some point).

In the following section, we explore the concerns embedded in the pragmatic approach in more detail.

3.2.3 The problematic nature of clinical trials

Thanks to the considerations presented above, the *pragmatic mentality* assumes that clinical trials have a potentially problematic nature. In this vein, Petryna (2009) stressed that pharma companies often use cost-benefit calculations in order to deal with adverse events, therefore creating conflicts between care and search for profits. This same point was made by some of my interviewees.

> "[...] We've seen a lot of cases, drug companies that keep making this calculation where they say: 'We did it and a tiny fraction of the cases... For most people, it helped them, and for a tiny fraction, people got terrible sick and died a terrible death. But it is very small. And so we figure out that if we sell a billion dollars of this drug in a year, ten people will die a horrible death and, if they all sue us, we figure it is going to cost...' So they start saying: 'Well, dying a long, horrible death isn't a reason to stop the drug. If that happens, then we have to figure out how much they will sue us for, how much we will have to pay, and: is it worth it?' [...] I do think that drug companies have to always be taking the marketization of their drug into account and into all their calculations. That is how the system works. So the role of the ethics committee is to try to understand that logic and monitor it and then keep it from getting too... too, you know, dangerous."
>
> (Cape Town/C7/Social scientist/08-11)

What is more, pragmatic claims stress that in addition to holding financial interests, companies make sure that such interests are continuously hidden from the public's eyes.

> "*Do you think there is any difference between a study that is done by a physician, a researcher, and a study that is done by the pharmaceutical industry?*
> Of course, many times the interests can be different, you know. Because, for instance, the pharmaceutical industry is purely concerned with capitalism, earning money, promoting a medication... I think in this research, there is a good and a bad side, but the bad side will never be very clear. It will never be very clear."
> (São Paulo/C2/Nurse/04-11)

> "*But do you think that these differences can increase the probability of harms in the research proposed by the industry?*
> Do you mean, is it the industry potentially more harmful than academic research?
> *Yeah.*
> [...] I think drug companies do have a lot more resources than us. And they're a lot harder to penetrate in terms of transparency and accountability [...] If I think that a professor is doing too much research and is starting to put together too many projects and is not doing them well, I can go ask the head of department there to give me a list of all the projects or ask that professor to give a list of all the projects, and you can get it, because we're part of the same institution or the same world, in a way. But no drug company is going to be doing that [...] When you're trying to assess, in a study, the whole range of contextual variables that matter, it is much harder to learn about that [...]."
> (Cape Town/C7/Social scientist/08-11)

What is at stake here is the status of research subjects enrolled in clinical trials. Within the framework of highly advanced economic schemes, people's dignity and integrity would be jeopardized. Petryna (2009, p. 28), for instance, expressed her concerns with trial participants, claiming that: "Their particular characteristics make them resources visible not only to the state but to capital as well."

"*I would like to know whether you think there is any difference between academic research and research sponsored by the industry.*

There is much difference [...] The financial part, in the studies sponsored by the industry, is massive, is very strong, whereas academic research depends on national or local funding, which many times is not sufficient, right? [...] Another big difference is in terms of concepts. For the pharmaceutical industry, research subjects are many times research objects, they're people who are going to provide some data, whereas in academic research, which is conducted by a postgraduate student, there is greater contact with participants and, many times, participants are seen as human beings [...]."

(Brasília/C4/Physician/04-11)

This impression is further fostered by the presence of calculations and statistical methods, which are always mobilized in clinical trials. These procedures tend to be associated with the annihilation of spontaneity and humanity. As a consequence, what would derive from clinical studies "[...] is not a population of living beings with certain biological regularities, but rather a market of consumers characterized by purchasing trends" (Lakoff, 2005, p. 137).

By reading the quotes I have presented so far, some people might argue that we are dealing with huge truisms. However, this is precisely the point to be made here. *Background knowledge* is composed by elementary assumptions deriving from the direct observation of the world. Here, we could repeat Geertz's (1983, p. 89) description of common sense: "The world is what the wide-awake, uncomplicated person takes it to be [...] the really important facts of life lie scattered openly along its surface, not cunningly secreted in its depths." Thus, the pragmatic mentality should not be considered as a set of pre-given inclinations. We are not dealing with notions that would spontaneously emerge in the social actors' minds. Their appearance depends on immediate observation and experience. However, these notions impose themselves with overwhelming weight, insofar as they spring from immediate observations that can hardly be denied.

Nevertheless, it is important to point out that the pragmatic mentality does not only recognize simple facts; it also makes people be *concerned* with these facts. This does not mean that committee members become suspicious towards pharma

companies (at least, not at this *mental* level). It means that the recognition of pragmatic claims triggers a special attention, a sort of moral alertness.

> "*Do you think there is any kind of difference between clinical research which is done academically and clinical research which is sponsored by the industry?*
> Oh, I do think so. The issue of interests, right? […] I think, when it involves the pharmaceutical industry, it is also linked to... financial interests, to financial profits, you know [...] I think, because of this invasion of the scientific and biomedical domain by marketing interests, I think ethics committees should be more careful in analysing studies with funding from pharmaceutical companies, for instance."
> (São Paulo/C3/Social Scientist/05-11)

> "*Do you think there is any type of protocol that deserves more attention from an ethics committee?*
> [...] if it comes from a drug company, you know... A drug company would be followed up differently than a NGO that wants to go do a project, you know, just because you assume that the drug company has interests that are potentially at odds with the safety of the patients. You know, it is potential, I'm not saying it is, but it requires you to pay more attention. You know, if a very large Northern drug company comes down and says: 'Hey! We want to help you! We want to do this trial! It is going to be really good for you.' And we're like: 'Aaaah...'
> *[Laughter.]*
> That might be true but let's pause, you know [...]."
> (Cape Town/C7/Social scientist/08-11)

Therefore, "the profit motive of pharmaceutical companies" (Fisher, 2009, p. 95) must be not only recognized but also dealt with, especially by committee members who frequently engage in "conversations" with research proposals submitted by those companies. Financial interests are considered to have the capacity to compromise the scientific soundness of a protocol, the safety of people enrolled in a trial, and the future of research participants. Of 42 committee members interviewed in my fieldwork, 9 people mentioned the issue of post-trial access to medicines.

"*So you are concerned about the fact that there are foreign companies conducting clinical trials in South Africa.*

And also, I am concerned with standard of care. You might get the best standard of care during the clinical trial; when it ends, what happens? There is also a problem about post-trial access, and we saw it during the time of HIV, when they were coming to the country, trying anti-retrovirals, when the trial is over they go, the patient shows a better resistance but that person cannot access anti-retrovirals in the public sector [...]."

(Pretoria/C8/Bioscientist/07-11)

Thus the oblivion to which research subjects may be subjected is another problem deriving from economic interests. Some people seem to be concerned also with the so-called professional research subjects, who try to enrol in successive trials in order to receive monetary compensations for participation. The topic has been focused on in some social science studies (Fisher, 2009, Petryna, 2009, Shah, 2006, Abadie, 2010). Even though this topic brings us too close to the *communitarian mentality* (it is actually shared by the pragmatic and communitarian approaches), there is an important lesson to be gleaned here: in the pragmatic mentality, there is a special concern with practical, everyday issues. Eventually, all social actors (including companies, researchers and research subjects) tend to be seen from the viewpoint of their immediate purposes. They are almost converted into interested agents, who would be striving to maximize their benefits at any moment.

Therefore, the pragmatic mentality does imply an individualist perspective, in the sense that it assumes the existence of a plethora of agents taking decisions on the basis of their practical experiences. Thus, I am referring to the philosophical dimension of the word "pragmatic," which points to a mutual influence between the experiences of the world and the practical notions and decisions formulated by people. We are dealing with a practical, deductive reasoning, which derives general ideas from direct empirical observations.

As Figure 3.1 suggests, the pragmatic mentality holds the seeds of both the *instrumental* and *communicative rationalities,* because it is composed by two complimentary aspects. On the one hand, the pragmatic mentality fails to ideologically combine health research (an altruistic activity) with commercial enterprises (a

particularistic activity). Therefore, the pragmatic mentality entails concerns with individualities, possible conversations, intercomprehension, and these are the very seeds of the *communicative rationality* and its related *mentalities.* On the other hand, the pragmatic approach acknowledges the existence of individual agents taking decisions according to their own motivations. In this way, it legitimizes the search for egoistic goals, general yardsticks, reification, and other seeds of the *instrumental rationality.* Even though Habermas did stress the relevance that the *background knowledge* holds for both instrumental and communicative actors, he did not stress sufficiently that both *rationalities* have their roots deeply embedded in the *background knowledge*, thus sharing their social cradle.[22]

This is the complexity that hides behind the apparently simplistic claims of the pragmatic mentality. According to the classic explanation by Poincaré (1908), as soon as our research instruments become powerful enough, we can discover "simplicity behind complexity," as well as "complexity behind simplicity." In the case of clinical trials, the simple/complex assumptions of the pragmatic approach can be summarized as follows:

1. Research subjects look for the solution of their health problems
2. Pharma companies and CROs look for profits
3. Clinical researchers look for economic compensations and institutional privileges

By the way, these are the basic assumptions of interpretations that point to "[...] the commercial interests of the pharmaceutical industry and the health interests of consumers" (Abraham, 1993, p. 393).

As mentioned in the introduction, globalization is seen in a different light depending on the approach held by social actors. From a pragmatic point of view, globalization has to do with the global diffusion of economic schemes that are

[22] Habermas talked about "pragmatic reason" in HABERMAS, J. 1993. *Justification and application: remarks on discourse ethics*, Cambridge, Polity Press. This is the definition he gives: "Pragmatic tasks are informed by the perspective of an agent who takes his preferences and goals as his point of departure." (p. 5-6) Even though this definition does not differ very much from my idea of *pragmatic mentality*, it clearly attaches pragmatism to the *instrumental rationality*, taking it away from the *communicative rationality.*

potentially problematic because they tend to overshadow other types of preoccupation.

So far we have focused on concerns brought about by the occurrence of financial schemes in clinical trials. As we shall see subsequently, this is not the only source of pragmatic concerns.

3.2.4 Researchers and interests

By reading the quotes presented in the previous section, one might have the impression that in the pragmatic mentality, all problems disappear as soon as one leaves the world of industrial trials and reaches the realm of academic research. However, the practical and immediate observations of the pragmatic approach come to identify new challenges in academic clinical studies. The basic concern, here, is the close relation that some researchers maintain to companies. "The industry's ideological advantage is compounded by the fact that doctors are often willing allies of the industry […] Indeed, the industry and profession largely stand in a symbiotic relation" (Busfield, 2006, p. 308). In this way, there is no separation between a supposedly pure and a supposedly corrupt world, for "[…] it cannot be assumed that the social interests of scientists and scientific knowledge can be adequately discussed in isolation from each other" (Abraham, 1993, p. 428).

Obviously, ethics committee members are aware of these issues. One of my Brazilian interviewees, for instance, mentioned one research proposal she had reviewed, in which an important methodological flaw was detected. She declared to be surprised by the fact that the physician-investigator, who was capable to identify the problem, was nevertheless willing to go forward with the study proposed by a pharma company:

> "*But do you think that the researcher, in that case, didn't see it [the methodological flaw] or decided to overlook it?*
> [Laughter.] Yes, you'll keep that confidential, Edison [laughter].
> *Absolutely. Absolutely.*

> Well, I have the impression that there is a certain conflict of interests between the competence of the guy... You know, if you think about it, generally, the PIs [principal investigators] are doctors in that expertise area, and I imagine that this is the criterion of CROs when they recruit researchers for the industry, you know. If I, who don't work on the area and don't even have a bachelor degree in that area of medicine and pharmacology, can realize it, I can only suspect that there is a certain conflict of interests in the sense that the project involves much money, it is an additional money, even though it is not much money, it is an extra [...] And the person ends up not doing the review and assumes that the industry designs projects so nicely, that: 'Okay, we'll sign it. That is fine. How much will I get? Oh, okay. So we're done, I'm the principal investigator' [...]."

From the basic assumption that some investigators can also be seduced by economic interests, one can derive claims such as the one voiced by Shah (2006, p. 56): "Thousands of practicing physicians are enticed into witching their patients to new drugs through industry-sponsored postmarketing trials.'" Here, we are dealing with a well-known range of concerns that come under the label of conflicts of interests (Topol and Blumenthal, 2005). From this point of view, researchers would be not only researchers but "entrepreneurial agents" or "pharmaceutical emissaries" (Fisher, 2009, p. 35-36).

Other aspects that make researchers be interested agents are also considered. It is recognized that academic life implies the search for titles, degrees and prestige. Clinical research can then be used in order to pursue these egoistic targets. From this standpoint, researchers, even though they are not motivated by economic reasons, may end up reifying people and conducting research in too reckless a fashion.

> "*How would you define the main goal of an ethics committee?*
> I think it is to refrain the studies that aren't really coherent [...] There may be outcomes but the main goal will be the profits, in the case of industrial studies; or it will be the researcher's doctoral thesis. It is not only the industrial research. The researcher may do the research, write the thesis and abandon the patients afterwards, you know [...]."
> (São Paulo/C1/Physician/04-11)

"*Today, what is your main motivation in your work in the committee?*

[...] I am motivated because I know that wishing to present an important and outstanding academic work, some individuals forget that they have the social responsibility not to expose society to unnecessary situations. When I get these studies to evaluate, I ask the researchers to rethink and I ask what the project's purpose is [...] Because, frequently, the willingness to present a good work may prevent the individual to realize the consequences of the project. Every project has consequences [...] It is important for the individual to know that there is a limit, that the study, the research, the scientific growth have a limit, which is the respect to individuals [...]."

(São Paulo/C2/Nurse/04-11)

Some interviewees recognized that for many students, the conduct of a clinical study has become an obligation without which their degree cannot be obtained. Thus certain recklessness could be expected from this type of researcher. These considerations foster the basic pragmatic notion according to which all types of social agents are striving to reach practical and immediate goals. Eventually, the pragmatic approach comes to be applied to ethics committees themselves. The outcome is an image of committees being threatened, or even permeated, by many economic and academic interests, as we shall see in the following section.

3.2.5 Pragmatic committees

As we have seen, the pragmatic mentality foregrounds the presence of financial and academic interests in clinical trials, framing the conduct of studies as more or less problematic. In this approach, ethics committees would not be immune to the practical issues of everyday life.

In the pragmatic mentality ethics committees are perceived as another actor of an institutional (and frequently academic) environment. In some interpretations, committees are seen as institutional authorities judging the work undertaken by the researchers (Dixon-Woods et al., 2007, O'Reilly et al., 2009). For instance, Dixon-Woods and collaborators (2007, p. 799) pointed out that: "Applicants must 'submit'

(the verb is used explicitly) to the committee; must make full disclosures and display their credentials as competent, trustworthy researchers; and must permit the exposure of their proposal to critical scrutiny [...]."

Alternatively, committees can be seen as players subjected to economic and academic pressures realized via researchers. Of the eight committees I studied, I was able to interview four committee chairs (two in each country). These interviewees (but especially the Brazilian ones) declared that sometimes researchers get disappointed or angry toward some committee's decisions, and the committee chairs are sometimes personally targeted by such feelings. Normal members also declared that committee members can be put under pressure by greedy, anxious researchers willing to begin their studies as soon as possible. Eckenwiller (2001, p. 47) voiced a typical pragmatic observation by saying that: "It is [...] likely that many if not most IRB members are acutely aware of the financial environment in which they operate and of the importance of clinical research in their institutions' economic viability. Their professional lives are shaped by pressures to increase revenues."

> "*[...] Let's imagine that I'm going to work as a committee member.*
> Yeah.
> *What are the.... What is the advice you would give me so that I can be a good committee member?*
> [Laughter.] Stay away. [Laughter.] Sorry [...] you have to have an adequate amount of time. Secondly, I think, you must ensure that you're not going to be bullied, be... Bullied is a colloquial term... but pressured into going in one direction [...]
> *And who could put me under pressure?*
> [...] I mean, I've had situations in which I asked four or five questions [to the researchers who had proposed the study]. They will answer three adequately, two inadequately. So I go back to them, get more advice. They might have answered one of those questions half adequately [...] And then, pressure will come that we have to... We are supposed to give them an answer in a certain length of time. So you see what I mean? It is indirect pressure. It is more psychological than anything [...]."
> (Cape Town/C6/Physician/08-11)

However, there are occasions in which pressure assumes less psychological, and more concrete, forms.

> "*Do you think that reviewing and reading a protocol involves a subjective aspect?*
> Oh, absolutely. Several, right? [Laughter] [...] There must be, but I've never seen it explicitly, but I believe there are power relations [...] Let's say you're reviewing a project from a professor who is the chair of your department and your current boss. To what extent can you deliver an impartial analysis of the project, considering power relations?
> *Even though the professor won't know who the reviewer is.*
> Even though the professor won't know who the reviewer is. [Pause.] Because it is not a review... How do you call it? It is not a peer-review. It is not a review like the one that happens in scientific articles, you know. Here it is different. All the members sit in the meeting room. When people are given the list with the projects, they know what the projects you've been given are. It is not blind.
> *And this information circulates.*
> It may circulate. The secretaries know. Have you seen how many secretaries sit in the meeting room? There are four or five, I guess, in average [...] So it is not blind. I don't even know if it should be, but I am saying that to give an example that the subjective aspect is always present, you know, and power relations are always present as well."
> (São Paulo/C3/Social scientist/05-11)

> "*If I told you that I am going to work in an ethics committee, as a reviewer, what is the advice you would give me so that I can be a good reviewer and a good committee member?*
> [...] You should not say: 'Oh, this project is very fine, it is from my good friend, so I'm going to approve it.' I think you have to be very focused. For instance, sometimes there are some projects... You have friends and enemies within academia. If I see it is from somebody... I say: 'I'm not analyzing this project because I have conflicts of interest' [...]."
> (São Paulo/C1/Physician/04-11)

In the pragmatic mentality, committees are framed as social agents engaged in practical matters and solving practical problems. Once they are part of an institutional

environment, they may also hold "conflicts of interest." For example, Bosk and Frader (1998) admit that a certain committee may be willing to approve studies whose conduct could make its hospital appear high-skilled and modern.

Due to practical considerations, committee members may be pushed toward either the approval of research proposals (when these latter come from bosses or friends, for instance) or toward the refusal of projects. One interviewee considered the possibility of a committer member's refusing a project in a research domain he or she wants to pioneer:

> "[...] There may be people in the committee who would like to do the same type of thing and then, I'm just wondering how... how fair would they be to this person whose work they're reviewing, you know [...] I've often wondered... Say, if [the committee member] is a doctor working on HIV and there is an HIV trial coming, and if he's interested in the same things, how... subjective or objective would this person be when he reviews the trial? [...]
> *Ah, because he's involved...*
> In the same area, perhaps [...]."
> (Cape Town/C6/Nurse/08-11)

In the pragmatic mentality, the institutional independence of committees is framed as a resource of difficult conservation. That is probably why most interviewees think that committee members should not receive payments for the work they do. Of 31 members I asked this question to, 18 people condemned payments in ethics committees. Generally, interviewees fear the interference of too strong conflicts of interest. They tend to associate payments with murky motivations, professional committees[23] with regrettable compromises. There is no professional committee in Brazil but there are two in South Africa, both based in Pretoria and playing a central role in the South African ethics review system.[24] One of these committees participated in my study. I addressed these issues in an interview with one of its members.

[23] Committees that receive fees for their reviewing work.
[24] In South Africa, many studies include private hospitals and practices, which do not have their own committees. Therefore, the two professional committees tend to review all the projects involving private research sites.

"*As the committee is private, the members get paid for the work.*

Yes.

Okay. And do you think that because they get paid, they tend to do a better work compared to other committees?

I think so. I really think so. Because, you know, it is long hours and hard work and I... And I have to perform [...] I've heard from committees where members do not get paid and it is a problem. It is a problem to get members to attend meetings, it is a problem to get members to review documents, to make, you know, contributions to meetings because [...] they've got so many other things that they have to do [...]

But do you think there are fundamental differences between a private committee and other types of committee?

Hm, you know what, I think conflict of interests. We've got very little conflict of interests in our meetings [...] there is no conflict of interests whereas, I think, if you're in a institution, the chances of the investigator also being a member of the committee or the investigator-supervisor being a member of the committee or the head of the department where they're doing the research... So there is a lot of conflict of interests in institutions because the members and the investigators are both from the same group of people [...] So, I think, we're much more independent. You know, we don't have anyone to look at over our shoulder, knowing that, you know, if I am not going to approve your research tomorrow, you know, I'm your boss and... you know. And it happens. I mean, I've heard of a lot of instances where studies get pushed through because it is the head of the department that is doing that, or things like that. We don't have that problem."

(Cape Town/C8/Lawyer/07-11)

Thus, against the idea that in professional committees there are economic conflicts of interest (which tends to be a strong idea because it is embedded in the *background knowledge*), this interviewee mobilizes the idea of institutional conflicts of interest in non-professional committees (which also sounds like a good point because it is also embedded in the *background knowledge*).

To summarize, an ethics committee, in the pragmatic approach, is seen as one of the actors immersed in an institutional and hierarchical environment where practical targets must be pursued. However, there is another aspect that is put forward by the pragmatic mentality: hierarchies involve not only relations between the

committee and the research site but also relations within the committee itself. Generally, the majority of committee members are physicians, a profession which may be associated with professional arrogance. For instance, one committee member, who had been in the committee for only a couple of months by the time of our interview, told me that in her first meeting, she got surprised with the physicians' kind attitude.

> *"So you hadn't imagined that the meeting would be friendly.*
> No.
> *How did you imagine it before beginning?*
> I don't know, when you congregate several areas, and especially medicine... Medicine is very superior (that is what they think, you know), superior, the holders of power and knowledge, you know, they have access to science. They have an institutional solidarity. But at least the physicians who are in the committee are really friendly."
> (São Paulo/C2/Nurse/04-11)

Differently from this committee member, other interviewees claimed that they do feel the professional and scientific superiority of physicians. In many situations, members lacking a medical or scientific background, and particularly lay members, can feel intimated in the face of sophisticated methodological and clinical discussions.[25] In a study by Storch and Griener (1992), for instance, it is claimed that in Canadian hospitals, ethics committees constitute a space to which nurses have precarious access and in which they do not feel at ease. In the pragmatic approach to ethics committees, therefore, there is an underlying assumption that committees, instead of promoting debate and participation, are reinforcing hierarchical differences in research sites (Rothman, 1991, Bosk and Frader, 1998, Eckenwiler, 2001, Kohlen, 2009).

In my fieldwork, I was allowed to attend some meetings of two Brazilian committees and identified a non-verbal, almost symbolic hierarchical sign. Meetings happen during the working time of many committee members. Health professionals (nurses, physicians, laboratory workers and pharmacists) go to the meeting room wearing their white working clothing, which creates a clear visual difference in relation to lay members and social scientists, who wear informal clothes, as well as to lawyers,

[25] I come back to this topic in Chapter 5, section 5.3.6.

who prefer formal suits, ties or dresses. Some physicians, in addition to their white clothes, display a distinctive sign: they simply let the stethoscope hang round their necks during the whole meeting.

A Brazilian physician told me that due to his medical knowledge, he comes to be a sort of "advisor" in the meetings.

> "*You said you end up being a sort of advisor in the committee. Do you think that because you fulfil this function... [...] I mean, do you think that in the meeting, you fulfil an outstanding function?*
> It shouldn't be so, but, I mean, as sometimes my opinion has to be in terms of yes or no, in an alternative...
> *A scientific opinion.*
> Yes, or an opinion that, for instance, will solve a disagreement, you know, then, obviously, I'm in an outstanding position, but it shouldn't be so. I think that opinions are weighted in a balanced way there [...] But, for instance, there are particularities in the committee, and that is when the committee becomes strong, collectively. When I have a legal doubt, for instance, the lawyers will give their opinion.
> *And then they'll have an outstanding position.*
> Exactly. And there are not few situations when we have to look for advisory from the lawyers."
> (Porto Alegre/C5/Physician/05-11)

For people holding a particularly strong pragmatic approach, participation within the committee comes to be framed as a network of power relations, demanding wise strategies.

> "*Is there anyone in the committee that you consider as a friend?*
> [Laughter.] [...] I think there certainly are [...] Academia is ruled through all kinds of conventions and relations and hierarchies and things like that [...] Well, those things happen in the committee as well [...] Medical doctors often assume greater authority than other academics [...] So those, sort of, nuances of academic life, those, sort of, power relations in academia happen in that committee as well [...] So for instance, medical doctors in the committee play a very different role and have a very different

> stake than people who are not medically trained. And even more so social scientists or people with a social science background, including anthropologists, sociologists and some other people. They have a very different stake. They have less interest in the success of medical research or in medical research making profits or being profitable, and they have more stake in looking at the participants. So if you accept that that is true, and if you accept that those power relations are going on, then it becomes important to build blocks, to ally yourself with other people who have similar views [...] I only do that with people who I share something with. So they are mostly other social scientists on the committee and I sort of try to understand their views, I try sort of match or align my views to theirs [...] In the meeting, I do that because it is not enough on the committee to just say something, you need not to be alone saying it [...] *So sometimes you can prepare a sort of strategy for a meeting.*
> [Laughter.] [Pause.] Maybe, maybe not. I am not going to say that."
> (Cape Town/C7/Social scientist/08-11)

Therefore, the ideological alertness instilled by the *pragmatic mentality* is applied to different circumstances. Be it in their indirect relations to researchers or their direct relations within the committee, members are constantly invited to weight the implications of their practical actions.

However, it is important to note that at the level of the pragmatic mentality, we are not yet dealing with moral judgements. Even though people recognize the interplay of financial, institutional and professional interests, the pragmatic approach does not frame them in terms of good and bad events. That is probably why, in the quotes presented throughout this chapter, claims were frequently accompanied by cautious remarks such as: "I've never seen it explicity," "I'm just wondering" or "Maybe, maybe not." Here, committee members are only acknowledging the presence of issues whose assessment and judgment are postponed by the pragmatic mentality and must then be realized by other *mentalities.* The pragmatic approach is an endless source of concerns and dilemmas but when it comes to solutions and answers, it is completely sterile. As we shall see in subsequent chapters, other *mentalities* emerge to cope with the stimuli provided by the pragmatic approach.

3.3 CONCLUSION

The *pragmatic mentality* forms therefore the basis on which the committee members' communicative actions lie. In order to depict the widespread use of pragmatic claims, let us consider the following table.

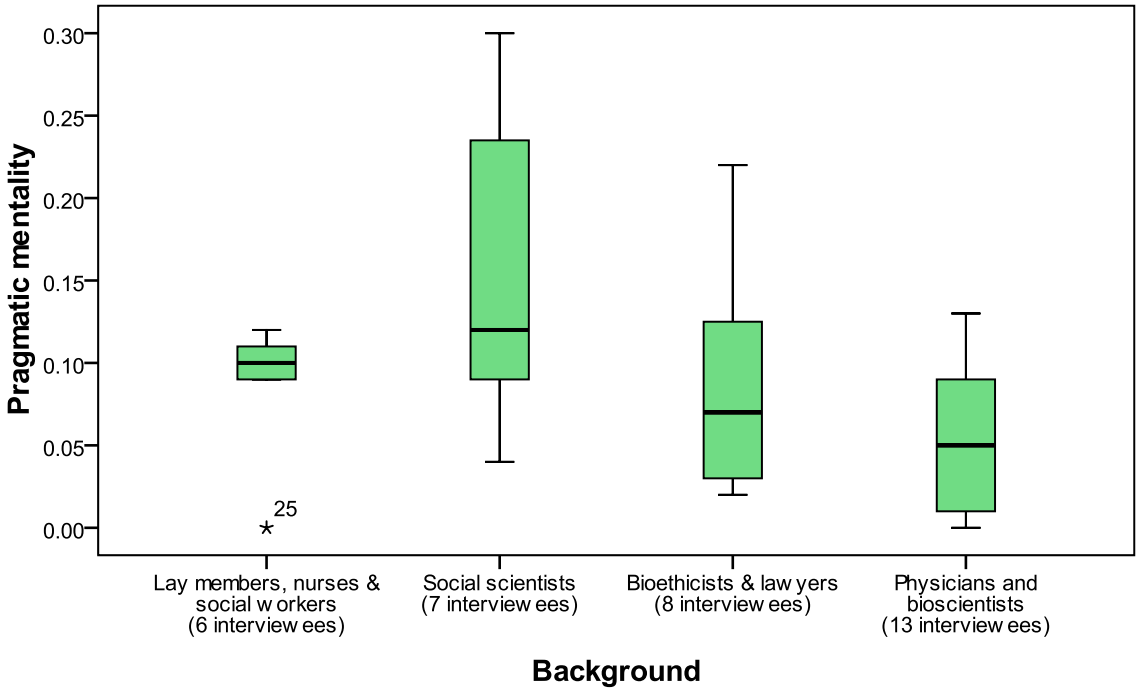
Table 3.1 – Occurrence of pragmatic claims according to country

Claim	South African interviewees	Brazilian interviewees	TOTAL[26]
"Pharma companies and CROs bring their financial interests to the universe of clinical research"	16 (94%)	13 (52%)	29 (69%)
"Researchers hold institutional and academic interests"	6 (35%)	7 (28%)	13 (30%)
"Due to financial interests, many research subjects do not have access to final products on completion of trials"	4 (23%)	5 (20%)	9 (21%)
"Ethics committees work under institutional and academic pressures"	4 (23%)	4 (16%)	8 (19%)

The table shows that pragmatic claims tend to be voiced by a considerable number of committee members.[27] The claim that stresses financial interests of the trials industry proved particularly widespread, being spontaneously voiced by 29 of 42 interviewees (and by 94% of my South African interviewees). Interestingly, there was a rather even distribution in both countries. However, there seems to be differences in terms of educational background, as shown in the following *discourse boxplot*:[28]

[26] The percentages on this column were calculated over the total number of interviews (42).
[27] It is important to remember that I let these themes emerge spontaneously during the interviews.
[28] The construction of *discourse boxplots* is explained in Chapter 2, section 2.6.

Figure 3.3 – Pragmatic mentality (South Africa and Brazil): discourse boxplots according to background



We can look at these boxplots as forming two layers. First, there is a layer composed by bioethicists, lawyers, physicians and bioscientists, who voiced pragmatic claims quite sparingly. The second group is composed by lay members, nurses, social workers and social scientists, who proved more willing to advance pragmatic claims.[29] Interestingly, this difference could be verified quantitatively, in spite of the small size of each group. By performing a statistical test,[30] I identified a statistically significant difference between these four boxplots (p=0.05). In order to verify where the difference really is, I performed another test,[31] comparing pairs of groups, and identified a significant difference only between the group of social scientists and the group formed by physicians and bioscientists (p=0.01).

Thus the acquisition of certain scientific knowledge (especially in biosciences and medicine) seems to undermine the proliferation of pragmatic concerns. When it

[29] Of the 34 interviewees considered in these boxplots, only one (represented by the number 25) diverged from this pattern. She is a Brazilian lay member who voiced no pragmatic claim.
[30] Kruskal-Wallis.
[31] Mann-Whitney.

comes to social scientists, the high performance in terms of pragmatic claims can be explained by their disciplinary emphasis on contextual factors, making them recognize and eventually accept some practical assumptions. In the case of lay members and nurses, one could expect higher levels of pragmatic claims. However, these interviewees seem to be over-concerned with their own lack of scientific knowledge, a preoccupation that prevents the pragmatic mentality from developing freely.[32]

Nevertheless, in spite of these differences, Table 3.1 offers good evidence about the widespread use of pragmatic claims, especially when it comes to recognizing the interference of financial interests in clinical trials. Thus few people would be willing to contest the basic idea that "[...] the main business of clinical research is not enhancing or saving lives but acquiring stuff: data. It is an industry, not a social service" (Shah, 2006, p. 176). To be sure, different ideological consequences can be derived from this elementary recognition, but if we focus on the recognition itself, forgetting its subsequent developments for a while, it can be said that we are dealing with the ideological force pointed out by Habermas (1996, p. 24), a force that is stronger than any social sanction based on social grounds or "plausible reasons."

By assimilating the contents of *background knowledge*, committee members are learning the basic rules of the game they are supposed to play. Once these essential rules are acknowledged, the challenges proposed by the pragmatic mentality can be ideologically dealt with. In fact, as soon as our attention moves from shared knowledge to ideological disagreements, we rapidly realize that in contemporary social groups, there is a good leeway for axiological differences. "The more societal complexity increases and originally ethnocentric perspectives widen, the more there develops a pluralisation of forms of life accompanied by an individualization of life histories, while the zones of overlapping lifeworlds and shared background assumptions shrink" (Habermas, 1996, p. 25). Thus the shared contents of *background knowledge* are not likely to become numerous and complex in a social life that promotes social and ideological differences. Such ideological differentiation happens, though, at a different level of the mental life, at which *background knowledge* turns into *foreground knowledge.* These differentiating process are focused on in the following chapters.

[32] We shall address this phenomenon in more detail in Chapter 5.

Chapter 4 – Background and foreground knowledge: the bioethical and communitarian mentalities

In this chapter, two new approaches to clinical trials are studied. Firstly, however, we introduce the concept of *foreground knowledge,* which will be important for understanding the relations between the basic pragmatic approach and other approaches. We then move on to analyzing several characteristics of the *bioethical* and *communitarian mentalities,* in a discussion that will involve the issues of vulnerability, risks, globalization and regulations, among others.

4.1 THE CONCEPT OF FOREGROUND KNOWLEDGE

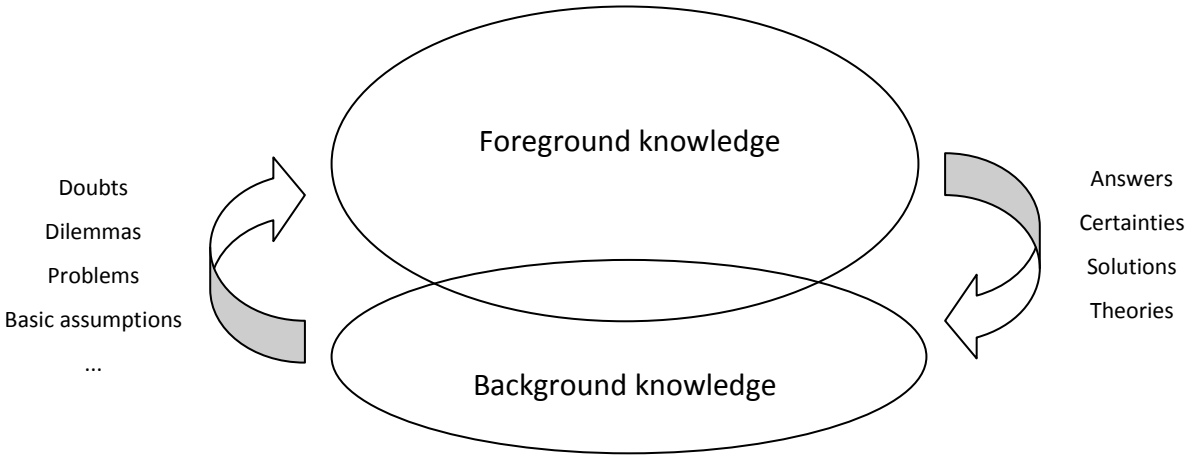
In the previous chapter, we focused on the *pragmatic mentality*, whose views about clinical research compose an ideological framework that can be interpreted with Habermas' (1981/1987, 1996) concept of *background knowledge*. It was claimed that certain notions become widely accepted and used by several types of social actors, therefore acquiring the status of almost taken-for granted ideas. Nevertheless, ideological life could not gain true consistency and permanency by only relying on practical, simple, intuitive background notions. There must also be a range of debatable ideas, which comprise the biggest part of our ideological life.

It was shown that the pragmatic mentality has a problematic nature, insofar as its typical claims point to dilemmas and threats that could transform clinical research into a reckless activity. Therefore, the pragmatic approach never ceases to provide stimuli and questions but fails to present ideological responses to solve these problems. In order to find out solutions, it is necessary to mobilize arguments, explanations, debates, comparisons, ideological challenges, among other resources which do not fit the superficial nature of pragmatic claims. In other words, the relatively simple assumptions of *background knowledge* bring about problems that demand much more sophisticated and systematized notions. It is necessary to build up what I propose to name *foreground knowledge.*

Even though Habermas did not propose a complementary concept to background knowledge, he did assume that in certain situations, notions lose their taken-for-granted status and begin to be contested and scrutinized. Therefore, *background knowledge* can sometimes be looked at in the light of social and political debates. “One can do this only by converting it from a resource into a topic of discussion, at which point – just when it is thematized – it no longer functions as a lifeworld background [...]” (Habermas, 1996, p. 22-23).

Thus, there is a crucial dimension of ideological life that requires debate, discussion and contestation, constituting the *foreground knowledge.* On the one hand, this knowledge is constantly stimulated by the dilemmas imposed by the *background knowledge.* On the other hand, foreground notions acquire the status of theories and explanations which are used to justify beliefs and claims embedded in the *background knowledge.* The following figure summarizes this circularity, which will be further studied in the present and next chapters.

Figure 4.1 – The circularity between background and foreground knowledge



Thanks to this *conversation*, ideologies can be nurtured by both the immediate force of *background knowledge* and the production of theories, which can only be formulated at the level of foreground notions. As a result, ideological life (or culture),

becomes not only real but intersubjective. “Culture, this acted document, thus is public […] Though ideational, it does not exist in someone’s head; though unphysical, it is not an occult entity” (Geertz, 1973, p. 10).

Ethics committees constitute an interesting space to study this circularity. On the one hand, as showed in Chapter 3, committee members are certainly informed by background notions. On the other hand, committees are also a space in which ideas and interpretations are discussed, therefore allowing the emergence of *foreground knowledge.* By presenting their views about particular research projects, as well as discussing general concepts of clinical research, committee members can refine their notions and therefore “experience meaningfulness,” to use Arendt’s (1958/1998, p. 4) telling expression. By discussing ideas, committee members acquire a “voice,” as Certeau (1990) would put it, in the sense that they express the reasons sustaining their convictions.

Whenever and wherever there is discussion, there are also impending dissensions. People engaging in debates must cope with the possibility of having their stances threatened or deconstructed. According to Habermas (1996, 2008), reasons are unstable insofar as they can always be confronted by other reasons that may be more powerful or consistent. For ethics committee members, dire threats must be continuously faced, especially in countries such as South Africa and Brazil, where clinical research has undergone a rapid expansion in few years.

According to Arendt (1958/1998, p. 252), “[...] history is a story of events and not of forces or ideas with predictable courses.” *Mentalities* can also be seen as ideological events of uncertain development. In this chapter, we explore the sources, features and political consequences of the *bioethical* and *communitarian mentalities,* which are largely responsible for the circularity between *background* and *foreground knowledge.*

4.2 THE BIOETHICAL AND COMMUNITARIAN MENTALITIES

In order to carry deep-rooted, immediate claims (*background knowledge*) and convert them into structured, debatable claims (*foreground knowledge*), a great ideological effort is needed. Several arguments and concepts have to be mobilized in

this passage. On the one hand, it is necessary to look for coherent associations of arguments, without which discourses rapidly succumb to the sway of opposing discourses. On the other hand, the realm of foreground knowledge does not involve practical and simple assumptions, as was the case in the pragmatic approach. Whenever discourses are to be debated and contrasted, they can no longer be simply informed by the unspecific evidences that prevail in background knowledge. Subjected to debate, they also need to be sustained by the projects, interests and specificities of those actors who voice them. In other words, their political and social *situatedness* has to be clarified; the first way to realize this task is to adopt a particular *rationality* (either the *instrumental* or *communicational rationality*).

These two basic ideological tasks (the construction of coherence and the adoption of one *rationality*) are conducted at the level of the *bioethical* and *communitarian mentalities.* This is why these two approaches are quite complex, in the sense that they hold several types of claims, *mental* connections and concerns. The following sections aim to present the basic features of these approaches. It is important to address them together, as they have some similarities, common preoccupations and, in some instances, share certain claims. In this sense, we will speak of *conversation,* referring to the fact that approaches do not have an independent existence. Without the supporting or conflicting voice of other *mentalities,* without engaging in *conversations*, one particular *mentality* would be nothing but a futile accumulation of clever arguments.

4.2.1 Vulnerability, deception, and protection

Elsewhere (Bicudo, 2011), I addressed the issue of "social exploitation" in global trials, stressing that for some social scientists, the exploitation of research subjects and developing countries is a pivotal concern. The pragmatic mentality proposes the image of greedy and untameable multinational companies willing to reach their targets by any means. There can emerge the idea that the action of global companies can have more devastating effects for some research subjects than others. This is one of the points of departure of both the *bioethical* and *communitarian*

mentalities: the idea that research subjects and countries, but especially the ones which are deemed more "vulnerable," are in need of protection.

> "*And in your opinion, what is the main goal of an ethics committee?*
> [...] of course, an ethics committee must focus on the research subject and look from there. I mean, you're working with people [...] So you must... I think an ethics committee must protect the study subjects."
> (Pretoria/C8/Bioscientist/07-11)

> "*In your opinion, what is the main goal of a research ethics committee?*
> Our main goal is to protect the public in which the research is going to take place and through which the findings of the research are going to be extrapolated. So that is the main aim, because they have nobody else that is going to speak on their behalf [...]."
> (Cape Town/C6/Physician/08-11)

Such concerns have to do with the historical and philosophical sources of the approaches focused on here. Both are inspired by examples of abuses and scandals that took place in past clinical studies, although they derive different conclusions from this evidence.

Even though the issues of vulnerability, exploitation and protection are common to both mentalities, they deal with them in a quite dissimilar way. In the *bioethical* approach, exploitation is said to emerge whenever crucial information is hidden from research subjects. Thus, people cannot fully understand the clinical study and take an autonomous, informed decision. To use Rapley's words, this mindset is highly informed by a "classic Kantian liberal version of autonomy":

> "This is a cognitive autonomy, where individuals are self-sufficient, with views, thoughts and decisions being generated 'from within', with the premise that we have a solo 'internal' state, that we 'own' our own thoughts, that we exist apart from our social relations" (Rapley, 2008. p. 434).

Clearly, ethics committee members cannot sustain this stance, which stresses the research subjects' individual autonomy, without being particularly conscious of

their own individual autonomy. Thus, it is possible to grasp one of the main features of the bioethical mentality*:* its being highly informed by individualistic references. As Habermas (1993, p. 6) noted:

> "Ethical questions by no means call for a complete break with the egocentric perspective; in each instance they take their orientation from the telos of one's own life. From this point of view, other persons, other life histories, and structures of interests acquire importance only to the extent that they are interrelated or interwoven with my identity, my life history, and my interests within the framework of an intersubjectively shared form of life [...]."

Because of this preoccupation with the provision of information in trials, the issue of informed consent to research has become a sort of mantra for many ethics committee members. In my fieldwork, out of 42 interviewees, 24 mentioned the topic, be it in a direct, indirect or ancillary way. From this point of view, the situation gets particularly tricky when one considers that in clinical trials, information is provided to participants through consent forms that frequently contain technical and scientific terms. A key task for ethics committees would therefore be to enforce explanations with which research subjects are made fully informed and let free to take decisions. Interestingly, in Brazil the consent form is called "informed and *free* consent form" (*termo de consentimento livre e informado*).

Obviously, it is frequently hard, if not impossible, to produce those utterly informed and autonomous subjects, a failure that has been interpreted with the typical bioethical idea of therapeutic misconception (Appelbaum et al., 1982, Fisher, 2006, Kimmelman, 2007, Lidz and Appelbaum, 2002, Madsen et al., 1999, Madsen et al., 2007).[33] In its search for a true informed, free consent to research, the bioethical mentality helps consolidate "[...] the withdrawal of the individual into an 'inward domain of consciousness' where it finds the only 'appropriate region of human liberty' [...]" (Arendt, 1963, p. 137).

[33] There have been efforts to commensurate and measure this so-called therapeutic misconception. As a result, a scale has been proposed. See CHOU, P. H. B. & O'ROURKE, N. 2011. Development and initial validation of the Therapeutic Misunderstanding Scale for use with clinical trials research participants. *Aging & Mental Health*, 16**,** 145-153.

In the *communitarian mentality*, vulnerability and exploitation acquire more concrete features. The problems are mainly associated with socioeconomic matters such as poverty and illiteracy. In this way, some groups, as a consequence of their social conditions, are framed as being less prepared to deal with the technical information, as well as financial temptations, introduced by global trials. Thus: "If the history of human experimentation tells us anything [...], it is that the potential for abuse will fall heaviest on the poorest and most powerless among us" (Shah, 2006, p. xi).[34]

The following table presents some examples of how these questions were addressed by my interviewees.

[34] On similar interpretations in the domain of social sciences, see BICUDO, E. 2011. "Geographical randomization" and "Social exploitation" in clinical research: world trials in Santiago, Chile. *Health and Place*, 17**,** 807-813.

Communitarian	Bioethical
"*Do you think it is possible to say that a committee has to protect people?* [...] that is a difficult question [...] because we also say that people need to be autonomous. But [...] I just want to stress that my personal view is that autonomy does not work very well in the context of medical research, because people do not always understand [...] In the evidence that we have that consent do not always work, in light of that evidence, and because people are mainly poor and mainly more vulnerable in this research context, I think we can assume that people have been induced to take risks [...] And I think in that context, this ethics committee does have a duty to protect research participants from taking risks [...]." (Cape Town/C7/Bioethicist/08-11)	"*Do you think that there is some part of the protocol that deserves more attention from a reviewer?* [...] I feel quite strongly that I try to maintain participants' autonomy in things like trials where one might say: 'Why is the company doing that study here? We won't get the medicines.' I do feel that, provided that it is safe, that actually should be the participants' decision. You know, if they are prepared to go onto the study, say, for two years, knowing for well that in the consent form they insisted that [...] they won't get the drug at the end of two years, I believe that is actually up to the participant to decide [...] So I'm a strong believer in not taking away autonomy [...]." (Cape Town/C7/Bioethicist/07-11)
"*Do you think there is any kind of protocol with which reviewers need to be more careful?* [...] I think the way you approach the research subjects is very important, because they are already in a delicate situation. It is not like the interview we're doing, because nobody is sick here [...] People can do everything to improve the situation, be it their own situation or that of another patient, you know. And here in the hospital, because it is an academic hospital, what I often see... I mean... The physician is god [...] I mean, we have very needy patients, so the physician is god. When they talk to the physician, they're almost talking to god. So the physician asks: 'Oh, do you want...' Sometimes, they get afraid [to say no] [...]." (São Paulo/C3/Bioscientist/05-11)	"[...] *Today, after these years of work, what is your main motivation to continue to work in the ethics committee?* [...] not to leave the research subject lacking basic information to take a conscious decision. Actually, what anyone wants in life is an individual issue. If a cancer patient has tried all the procedures without finding a solution for the disease and wants to take part in spite of the risks, I think that is adequate, as long as the person know what is being done. So the committee members... it is not up to us to judge personal things. We simply wish to make sure that research subjects are given adequate information so that they can take their own decision." (Porto Alegre/C5/Physician/05-11)

When talking about protection, people may be referring to different things, depending on whether they tend to embrace the bioethical or communitarian view. In bioethical terms, defending research subjects amounts to making sure that all relevant information is provided in the informed consent process so that people can take free decisions. This is a key target for a mindset that proposes the idea of "solving problems by ethical discussions and not by deeds" (Kohlen, 2009, p. 215). In the communitarian

approach, protection acquires a more concrete nature, having to do with the refusal of studies that might harm people physically.

Communitarian	Bioethical
"*But why don't you agree with this kind of oncologic trial?* No, I don't agree when someone is going to die [...] and you do an experiment on him. Because [laughter] you can give him a placebo as well. I'm sorry, you can't give a man who's dying a placebo [laughter]. *Yeah, but the industry would say that, maybe, the protocol could help to expand the life of these subjects.* But for how long? *For some months.* You can't... They don't know. They don't know for how long. But the man is suffering. He's suffering. Why extend his suffering? [...]" (Cape Town/C7/Community/08-11)	"*When you're reviewing a protocol, what is your main concern?* [...] Again, the patient is the focus, or the... the persons being (they're not always patients), the persons being researched. Those are the ones that you have to protect [...] You must see that they're not going to be exploited in any way. That you see that they get sufficient information. For instance, the information sheet and the consent form and all this, we go through them to make quite sure that the language... the person understands; that there is nothing in there that is a double message [...]." (Cape Town/C7/Nurse/07-11)
"*In your opinion, what is the main goal of an ethics committee?* In my opinion, it is protection of the participants [...] We are seeing more and more pharmacogenetic studies, blood is collected or samples or blood or tissues or whatever, sent overseas and we've got capacity in our country to do that. So what one sees is intellectual property. It is going out. And we think it must be discouraged [...] Then they know everything about our DNA and we don't know anything about it. So South Africa is far-advanced, probably Brazil too. They can come and build capacity, and the tissues should remain in our country, the samples should remain." (Pretoria/C8/Bioscientist/07-11)	"I think that the correct thing would be to offer training courses to teach researchers about the proper ways of presenting an informed consent form [...] You have to inform people and let them free to choose, instead of deviating them towards the side you want them to direct their consent, you know." (São Paulo/C1/Bioethicist/02-11)

As the two quotes at the bottom show, in the bioethical mentality, concerns with the consent form are extended to the consent process whereas the communitarian mentality generates a concern with the body, extending it to samples extracted from bodies and displaying an unease with a potential "commodification of the body" (Scheper-Hughes, 2000). This communitarian concern with samples is not

surprising, for as Haddow (2005) argued, organs and other bodily parts are frequently framed as the continuation of people's bodies.

Actually, we are in a murky zone, where both mentalities share strong claims but, at the same time, have strong disagreements. As the quotes above show, the issue of autonomy, which is so important within the bioethical discourse, is almost despised by the communitarian approach, which foregrounds contextual factors undermining free choices and autonomy. However, the quotes also let us see that these approaches can be combined quite smoothly. The following example is a single reply given by one interviewee and broken into different parts according to the mentality conveyed:

Question	"*Do you have an example of an ethical problem in clinical research?*
Bioethical	Well, it would be under all the main heading of beneficence. So who benefits from it? You know, if the participants don't benefit at all and they're taking all the risk, then that would be a problem.
Communitarian	If persons are going to have severe side effects and they're not well-looked after afterwards, you know, so what kind of care does a person that gets injured during the study... do they have any care? Does anybody follow-up on them or do they fall back on themselves? Are there any resources allocated for that?
Bioethical	Are they properly informed?
Communitarian	You know, we've got eleven official languages in South Africa.
Bioethical/Communitarian	So do they only take the consent in English? How well is the consent taken in the other languages? So where do you want to do the research? Depending on where it is in South Africa, there is a dominant language in that area. So do you have translated materials, for instance? [...]" (Cape Town/C6/Physician/08-11)

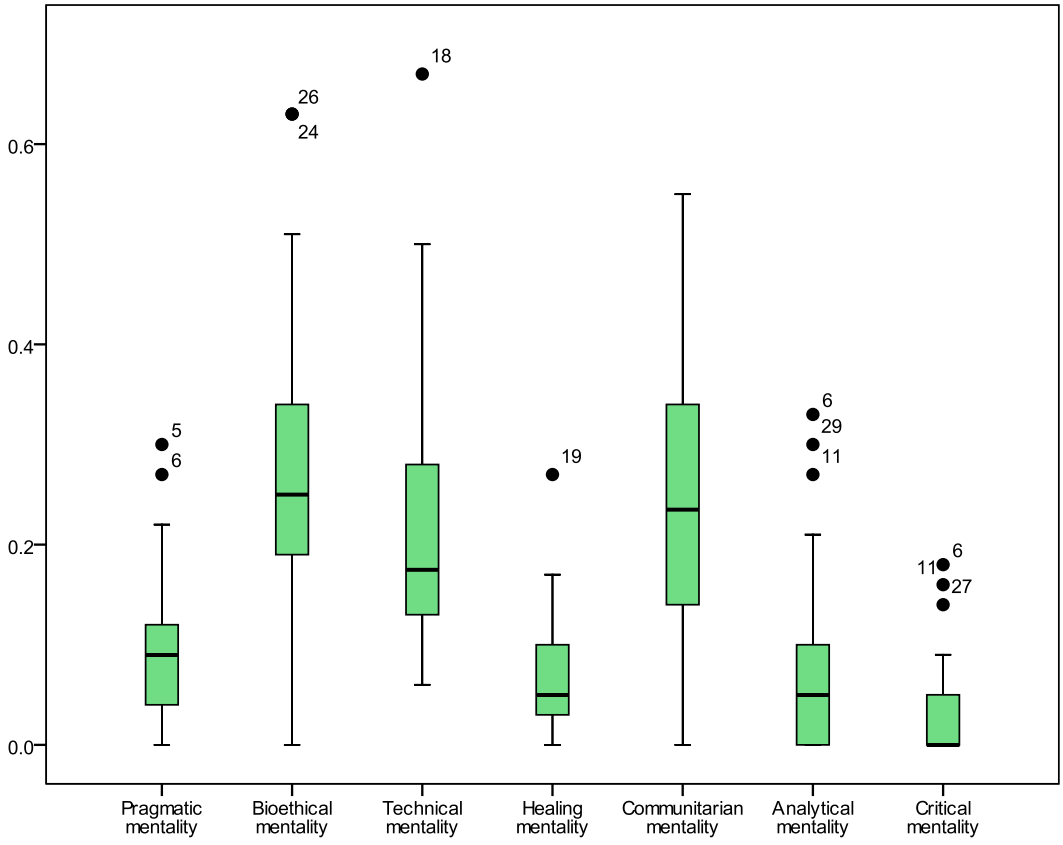
This interviewee came to take a communitarian concern (the existence of different languages in South Africa) and mix it with the issue of informed consent, a typical bioethical point.

These two mentalities take the basic concerns of background knowledge in order to build more systematic discourses. Because of this capacity to generate *foreground knowledge* from *background knowledge,* and also because of their manifold blends, the communitarian and bioethical discourses seem to be the ones

which are the most frequently voiced by committee members. The following *discourse boxplots* give us an idea.[35]

Figure 4.2 – Discourse boxplots according to mentalities

34 strong interviews (16 in South Africa, 18 in Brazil)



Performing a statistical test,[36] I verified a large statistical difference between these boxplots.[37] We can see that, compared to other *mentalities,* the bioethical and communitarian ones were voiced in greater proportions by my interviewees. Their average proportions (0.27 and 0.24 respectively) were indeed very close to each other. The *technical mentality* seems to occupy an intermediate position (the average score

[35] On the methods used to build up these boxplots, see Chapter 2.
[36] Friedman's test.
[37] The p value is less than 0.0005.

was 0.22).[38] Finally, the other mentalities displayed low scores (their average score were either equal to or less than 0.08).

The diffusion, agreements and disagreements of the bioethical and communitarian mentalities have to do with their historical sources and developments, which will be discussed in the following section.

4.2.2 Philosophical and historical sources

As claimed in the previous chapters, mentalities derive from long historical developments. The mentalities which are focused on in this chapter have been decisively influenced by hazards and scandals taking place in clinical research, but they deal with these issues differently.

The bioethical approach has been fostered and shaped by stories that circulate in the world of clinical trials, talking about deception, deaths, abuses and exploitation. I am referring to past examples such as the thalidomide scandal (Petryna, 2009, Timmermans and Berg, 2003), the Tuskegee study (Rothman, 1991, Angell, 1997, Lederman, 2006, Epstein, 2007, Petryna, 2009, Kohlen, 2009), the experiments with prisoners in the United States (Rothman, 1991, Epstein, 2007, Fisher, 2009, Petryna, 2006), the Willowbrook study with mentally retarded children (Kohlen, 2009, Bosk, 1999/2008), the Aids studies in Africa (Epstein, 2007, Petryna, 2006), or the studies conducted without informed consent with victims of the Bophal accident in India (Chattopadhyay, 2012).[39]

Another famous case, the Trovan trial (Petryna, 2006) conducted by Pfizer in Africa, has even inspired *The constant gardener*, a 2001 novel by John le Carré, subsequently adapted into a film. In my fieldwork, this book was cited by an interviewee in Cape Town whereas the film was mentioned by a committee member in São Paulo. In the following quotes, we have two examples of interviewees referring to past scandals in clinical research.

[38] However, I shall make an important qualification in Chapter 5, section 5.3.6.

[39] For numerous and detailed examples of gloomy, cruel experiments with human beings, see MORENO, J. D. 2000. *Undue risk: secret state experiments on humans*, New York ; Basingstoke, W.H. Freeman, 1999. and SHAH, S. 2006. *The body hunters: testing new drugs on the world's poorest patients*, New York/London, New Press.

"*Do you think the analysis of a protocol involves a subjective dimension?*

[...] Let's say it is an ideological, rather than subjective, dimension, perhaps, especially when it involves multinational companies, because they have bad name, because people know that some companies used disabled and vulnerable subjects to conduct some unnecessary studies, especially outside Brazil, you know. There are so many news that come from Africa and even the United States, talking about the past use of sick people, prisoners and so on in certain studies that were somewhat inhuman [...]."

(Porto Alegre/C5/Lawyer/05-11)

"*In your opinion, what is the main goal of an ethics committee?*

I think it is to protect patients [...] They can't know beforehand what is going to happen to them. So there must be an intermediation, which prevents abuses [...] Since the first studies... I mean, what the Germans did to Jews, what the Americans did to black people in prisons, what some schools did to poor students. There was nobody to protect them [...]."

(São Paulo/C2/Physician/04-11)

In the bioethical mentality, such examples are used as evidence in order to claim for regulations and principles with which the protection of research subjects would be streamlined. Not surprisingly, then, the principle of informed consent to research, which is nowadays so important for this mentality, was firstly stated in the 1947 Nuremberg Code, whose writing was firmly motivated by the Nazi research abuses carried out during the Second World War. Some stories can also become locally or nationally famous, as is the case of a malaria study once conducted in Brazil.

"[...] some things cannot be justified. For example, in a malaria study, infecting people with malaria, with mosquitoes biting people and then giving them a medicine to see whether it is effective for malaria, this should not... Right? So in order to know if that medicine is effective for malaria, should I first infect people with malaria? There are so many people who already have malaria. Why should I expose people to this risk?"

(São Paulo/C1/Physician/04-11)

Of 42 interviewees, 10 recalled past abuses in trials. I got intrigued by the constant repetition of these stories. It seemed to me that I was facing not only an effort of remembrance but also an effort to organize ideas and examples. As Arendt (1963, p. 222) claimed:

> "[...] if it is true that all thought begins with remembrance, it is also true that no remembrance remains secure unless it is condensed and distilled into a framework of conceptual notions within which it can further exercise itself. Experiences and even the stories which grow out of what men do and endure, of happenings and events, sink back into the futility inherent in the living word and the living deed unless they are talked about over and over again."

By analyzing the structure of stories of scandals in clinical trials, I discovered the presence of a general pattern, as summarized below:

I. Greedy, interested actors wish to conduct a clinical study
II. Using regulatory and social loopholes, the study is conducted, causing harms and deaths
III. Regulatory and social tools are created to prevent new scandals
IV. New loopholes appear slowly, enabling the conduct of new forms of abusive studies

In this way, it is possible to go back from step IV to step I, and the circle never ceases to be repeated. This way of thinking can be interpreted as mythical thought, in Lévi-Strauss' (1958/1974, p. 231) terms:

> "A myth always refers to past events [...] However, the intrinsic worth that is attributed to it depend on the fact that these events, considered as having started at a given moment, also constitute a permanent structure, which refers simultaneously to past, present and future."

Indeed, in the stories repeated in the domain of clinical research, it is possible to identify a series of “symbolic operations” such as those which are described by Lévi-Strauss (1958/1974, p. 248):

> “The mythical thought derives from the consideration of certain oppositions and tends to mediate between them progressively. Let us say that two terms, between which the passage seems impossible, are firstly replaced by two equivalent terms that can be mediated by a third term. Subsequently, one of the extreme terms and the intermediate term are, in their turn, replaced by a new triad, and so forth.”

The following table applies this description to clinical studies’ myths.

Table 4.1 – Symbolic operations of the bioethical mentality

Operation	Selected pair	Triad
1st	Good Bad	*Health* *Drug* Illness
2nd	Health Drug	*Benefits* *Research* Risks
3rd	Benefits Research	*Patient* *Consent process* Researcher
4	Patient Consent process	*Need* *Information* Interest
5	...	...

The first pair is "Good and Bad," for as we shall see,[40] this is the moving dyad animating the bioethical approach. This pair, which seems irreconcilable, is subject to a replacement: "Good" is replaced with "Health" whereas "Bad" is replaced with "Illness." "Drug" appears as the mediating term that links the extreme terms together. Subsequently, in the second operation, "Health and Drug" are selected to form a new pair, which goes through a new replacement, and these operations can be endlessly repeated. It is important to stress this mythical nature of the bioethical mentality in order to understand two of its pivotal philosophical and political features.

Firstly, there is great capacity to cope with frustrations and contradictions. Apparently, for instance, there is no way to reconcile the use of placebos in clinical trials with the health needs of research subjects. However, these two terms ("Placebo and Need") can be replaced with new terms, like "Risks and Benefits." Thus, we would be right in the third operation of the previous table, ready to introduce a new term: "Consent process." The resulting discourse would be something like: "In spite of placebos' being at odds with the research subjects' health needs, such risks must be incurred in order to glean benefits, in a procedure that is acceptable as soon as people are informed about what is going on." Even though such operations and discourses may sound weak or even cynical, their widespread use testifies to their philosophical and political efficacy. Eventually, there is no ethical matter or scientific antinomy that cannot be tamed by means of bioethical symbolic operations. This is why it can be said that "[...] the myth is simultaneously in language and beyond it" (Lévi-Strauss, 1958/1974, p. 230). This is also why the *bioethical mentality* has been proving useful not only for committee members (who assess the worth of research proposals) but also for clinical researchers and the trials industry itself (that can justify even their most heterodox research methodologies). This cultural capacity to accommodate almost every controversy is the very source of what Guillemin (1998, p. 60) called the "inherent conservatism" of bioethics.

Secondly, the bioethical approach tends to be globalized quite swiftly. Mythical thoughts depend on a particular structure (such as the one which was presented in the previous table), and not so much on particular contents. Thus mythical stories can be

[40] Section 4.2.3.

efficaciously repeated no matter what the language is. As Lévi-Strauss (1958/1974, p. 232) explains:

> "[...] the worth of the myth as myth is preserved in spite of translations. However big our ignorance about the language and the people's culture from where it is collected, a myth is perceived as myth by every reader, all over the world. The substance of the myth lies neither in style nor in the mode of narration nor in syntaxes, but in the *story* that is told."

This is why I could come across the same *stories* in interviews conducted in cities as different as São Paulo, Brasília, Pretoria or Cape Town.

The *communitarian mentality* has different sources. Although indirectly, the classic study conducted by Renée Fox (1959/1998) helps us understand its basic features. Focusing on a research ward located in a teaching hospital, Fox explored the uncertainties faced by some physicians who had to provide health care to, and conduct research on, terminally ill patients. That group of physicians/researchers had to deal with diseases whose causes and features were barely understood at that time. "Partly as consequence, many of the experiments conceived by the Group were highly empirical in nature: 'trial and error shots in the dark' of which the outcome was very uncertain and unpredictable […]" (Fox, 1959/1998, p. 31).

Even though medical knowledge is currently more sophisticated, as opposed to the situation of the 1950s, uncertainty could not be rubbed out from clinical experiments. To a good extent, James Conant's words, quoted by Fox (1959/1998, p. 31), continue to be valid: "In spite of an enormous amount of experimentation by chemists in making new substances and pharmacologists in testing then on animals and on men, one can say that it is almost impossible to predict the action of a chemical substance of a given structure on a human being […]."

Such uncertainties exist not only at the stage in which drugs are prospected and assessed but also at latter moments, when final medicines are already on the market. On the one hand, there are many examples of drugs being commercialized for many years and being subsequently withdrawn from the market because of harms and deaths they had provoked (Busfield, 2006, Fisher, 2009, Petryna, 2009). On the other hand, clinical response to drugs depends on individual biological characteristics, which

prevent us to be sure that a certain medicine will have the same beneficial effect for every person. It is known that approved medicines frequently provoke adverse reactions and hospitalizations. Thus uncertainty is not only typical to clinical research but can also be found in health care at large, even though it reaches higher degrees in that first phase in which new therapies have not been established yet.

What is more, every clinical study combines traits of experimentation with traits of care. Such circumstance was grasped by Fox (1959/1998, p. 53), who said that in the ward she studied, physicians had to solve a "[...] conflict between their obligations to advance knowledge and their responsibility to promote the welfare of their patient-subjects." In a clinical study, personal relations and human idiosyncrasies may, as it were, compromise the accuracy of medical and statistical tools. Mueller (1997, p. 68), for instance, talks about "close relations between nurses and patients" in clinical studies. In this way, clinical trials combine not only the advantages of experimentation and care (whatever they might be) but also their uncertainties.

In the bioethical mentality, research and care are clearly separated. By the way, the idea of therapeutic misconception relies precisely on this separation. One research subject will be said to hold misconception whenever he or she is not able to clearly understand that a clinical study is being undertaken, excluding logics and relations typical to health care. In the communitarian mentality, however, research and care can never be disentangled. In addition, the communitarian approach does not operate with mediating, alleviating terms such as the principle of informed consent. Here, uncertainties and paradoxes cannot be circumvented. There is no way to deprive trials of their problematic, uncertain features. Recognizing the insurmountable gray areas defined by trials is indeed a basic feature of the communitarian mentality.

> "*And do you think that committees, nowadays, are well-equipped to prevent harm in clinical research, in the way they are organized today?*
> [...] I think they do their best. Some harm is bound to happen. You know, it is not bound, but harm does happen [...] 'Cause research... A lot of research that is not in a laboratory and it is with people often leads to messy things. It is not... You know, it is not neat. It is ups and downs [...]."
> (Cape Town/C7/Social scientist/08-11)

"[...] What was the question again?

What is the main goal of clinical research. The main target.

[...] As I said, trials should be done in a safe way. I know that it is unpredictable how drugs would... their effect on the body if they've been studied for the first time, but, still, the people doing the trial should try and limit the effects or side effects (as much as they can) of the drugs that they're testing [...]."

(Cape Town/C6/Community/08-11)

Thus even though people expect that risks can be minimized, they acknowledge that there will always be uncertainties in experimentation. From this point of view, the passage from health care to clinical research is always deemed a problematic event, for experiments are thought of as holding more uncertainties.

"*Does it take time to review a protocol?*

[...] Obviously, when patients are involved, one has to be extra-careful that one isn't withdrawing treatment. In fact, one of the trials we're looking at today[41] is... someone wants to withdraw recognized treatment and replace with placebo, which I think that has got very major ethical consequences [...]."

(Cape Town/C6/Physician/08-11)

Withdrawing treatment, and going from health care to research, will always be seen as problematic in the communitarian mentality. This mentality has emerged not because of examples of researchers acting unwisely, as was the case for the bioethical mentality. In the communitarian approach, one can never be certain to act wisely enough. Such dilemmas can only be intensified by the evidence that many studies are conducted with people generally considered as socially and economically vulnerable. Hence, some claims like the one advanced by Fisher (2009, p. 32): "The poor and uninsured have become the groups whose disenfranchised bodies are used in the name of medical progress and pharmaceutical profit."

Here we get to the core of the communitarian philosophical underpinnings: the element of compassion. As Hannah Arendt explains, compassion, as a social moving

[41] This interview was conducted right before the committee meeting.

force, was discovered during the French Revolution. At that time, but also today, its main expression assumes the form of feelings flowing from advantaged people towards disadvantaged people.

> "What counted here, in this great effort of a general human solidarization, was selflessness, the capacity to lose oneself in the sufferings of others, rather than active goodness, and what appeared most odious and even most dangerous was selfishness rather than wickedness [...]" (Arendt, 1963, p. 76).

On this point, the choice of South Africa and Brazil proved particularly interesting for my study. Due to their vast populations of poor people, these are countries where the communitarian approach is most likely to emerge and become strong.[42] Obviously, compassion was not a motive of which my interviewees spoke openly. However, the analysis I am proposing, as well as many other types of analyses, would be impossible without going beyond what is explicitly said. Moreover, it is important to consider that in the communitarian mentality, feelings play a major role. As we shall see,[43] people holding this approach are willing to imagine themselves in the research subjects' place. Compassion is certainly a driving force that allows realizing this intention, weakening barriers and mediations between men.[44]

Thus there is much leeway for passion and compassion, in a sort of emotional stance that people can barely translate with words. "Passion and compassion are not speechless, but their language consists in gestures and expressions of countenance rather than in words" (Arendt, 1963, p. 81). Indeed, people who tend to embrace the communitarian mentality are the ones which frequently struggle to convey their thoughts in a precise way. Such difficulties became clear to me in the course of some interviews, like in the following example.

[42] Both the English and Portuguese languages share a characteristic that occurs in some other languages: "poor" (or "*pobre*") can be either a noun (meaning someone having few economic resources) or an adjective used to describe people (meaning someone who inspires compassion).
[43] Section 4.2.7.
[44] When a drug proves to be beneficial for research subjects in a phase 3 trial, the study's sponsor can organize a new trial, with the same study population, so that people continue to access the drug until regulatory approval is eventually issued. Such type of pre-approval study is often referred to as "compassionate use."

"*In my observations of the meetings, I had the impression that you're concerned about samples being sent abroad.*

Yes.

And why?

Ah, again, I think the objective of the scientific enterprise is to do good science. So it shouldn't matter where that science takes place, and it is equally unethical to argue that you cannot send any samples abroad for scientific investigation if South Africans themselves do not do the research, right? Doing research is not just a right, I think it is also a duty. So just as scientific researchers in South Africa can't claim to... to have a... Okay, let me just stay there. So doing scientific research is not just a right, it is also a duty, right? That point is quite important for me [...]."

(Cape Town/C7/Bioethicist/08-11)

While this interviewee was trying to formulate the answer cited above, I had the impression that she presumed that her explanation would be much more straightforward than it really was. Indeed, holders of the communitarian approach feel the emotional force of their stance but face difficulties to express it systematically.

Some approaches (especially the technical and bioethical) are driven by almost ready-made concepts and tend to be more "talkative." They are marked by this "cold-blooded" attitude that according to Mauss (1936, p. 22), can be described as a "[...] mechanism that slow things down and inhibits uncoordinated movements; by slowing things down, this mechanism enables a coordinated response composed by coordinated movements going towards the chosen goal." In its turn, the communitarian discourse depends on personal and sometimes emotive choices to be conveyed. It is the approach of cut sentences, oral attempts and pauses. It could be said that, in their task to transform *background knowledge* into *foreground knowledge*, the bioethical mentality is faster and more efficient than its communitarian counterpart.

In order to further explore the features of these approaches, we move on to addressing the question of risks in trials.

4.2.3 The issue of risks

The previous considerations are important to understand how the bioethical and communitarian approaches frame the issue of risks in clinical research. In the bioethical mentality, one never speaks simply about risk. According to the binary bioethical logic, there must be an opposing element, which comes to be the idea of benefit. Hence, the famous idea of a risk-benefit ratio in clinical research.

> "*Among the several projects that get to the committee, do you think there is any type of project that deserves special attention from reviewers?*
> [...] We're always more careful with sponsored [by companies] studies [...] But [...] everything we do with patients in medicine involves risks and benefits. Risks should never outpace benefits. Benefits should always win. So you always have to assess that. The benefits of the study will be good, but are risks bigger than benefits? [...]"
> (São Paulo/C1/Physician/04-11)

> "*But do you think that when you're reviewing an industrial protocol, you have a different stance toward the protocol?*
> No [...] I'll be very careful, especially if the medicine has not been approved in the country, you know... Because I'm concerned about the risks that the procedures (which include medicines in the case of clinical trials) will offer to research subjects, you know, and about doing the right balance between risks and benefits [...]."
> (São Paulo/C3/Social scientist/05-11)

One of the bioethical mentality's biggest deeds was the introduction of calculation into the realm of ethical committees. Actually, efforts to apply objective calculations in subjective and moral questions have been present for a long time. According to Arendt, Bentham provided a decisive contribution for this project by proposing his "pain and pleasure calculus," "introducing the mathematical method into the moral sciences [...]" (Arendt, 1963, p. 309). When it comes to clinical research, moral calculations are always referred to the individual life, which as Arendt (1963, p. 311-312) explains, has become the "supreme standard" in modern society.

In the bioethical approach, research has good dimensions, for it enhances the human existence, but also many sorts of drawbacks, for individuals may be harmed in the course of studies. At the very core of the bioethical mentality, we find this endless search for the good, which is typical to the sphere of ethics (Habermas, 1993). In addition, goods and bads are thought of as elements of a calculation. As Mazur (1985, p. 26) explains, the risk-benefit perspective assumes:

> "[...] (a) that goods and bads are commensurable in the sense that they can be measured by some common metric so that one can be compared against another; (b) that goods and bads *should* be traded off against one another; and (c) that the person or group can maximize its utility by maximizing the net profit of goods-minus-bads."

Of course, the idea of a risk-benefit ratio, or a balance between risks and benefits, expresses an important amount of linguistic freedom: it suggests an objectivity that cannot really be realized in the assessment of clinical protocols, because different committee members can obviously get to different ratios. However, the philosophical target here is not the introduction of numerical calculations but the conduct of moral ethical calculations whereby an initial element (risk) can be complemented by another element (benefit), thereby underpinning the bioethical *symbolic operations*.[45]

Once again, we are in front of a successful and widespread idea. Out of 42 people interviewed in my fieldwork, 16 referred to the risk-benefit balance, be it in a direct, indirect or ancillary way. As Hacking (1990, p 4) points out, the idea has become a sort of official rationale for many types of decision makers, who therefore tend to "replace judgement by computation."

With this rationale, people can assess not only particular research projects but also broader phenomena taking place in society. Hence the occurrence of claims such as the one voiced by Shah (2006, p. 164): "[...] just as ethics committees evaluate the risks and benefits of individual trials, society must evaluate the risks and benefits of the entire business of human experimentation." In this way, by enabling the conduct

[45] See section 4.2.2.

of moral calculations, the bioethical mentality brings about a "proto-objective" logic that will be further developed by the technical mentality.

This is another source of this approach's force. The bioethical mentality, by making it possible to "quantify" and "objectify" moral reflections, has filled a pivotal gap within the universe of *instrumental rationality*. Thanks to it, one can tame the uncertainties and threats presented by the pragmatic approach, moving towards the technical approach rather smoothly. In the previous section, I claimed that the bioethical approach operates by mediations. Now we see that it is itself a mediator (assuming an ideological position between the pragmatic and technical mentalities), and this is also why symbolic, mediating operations are so crucial to it.

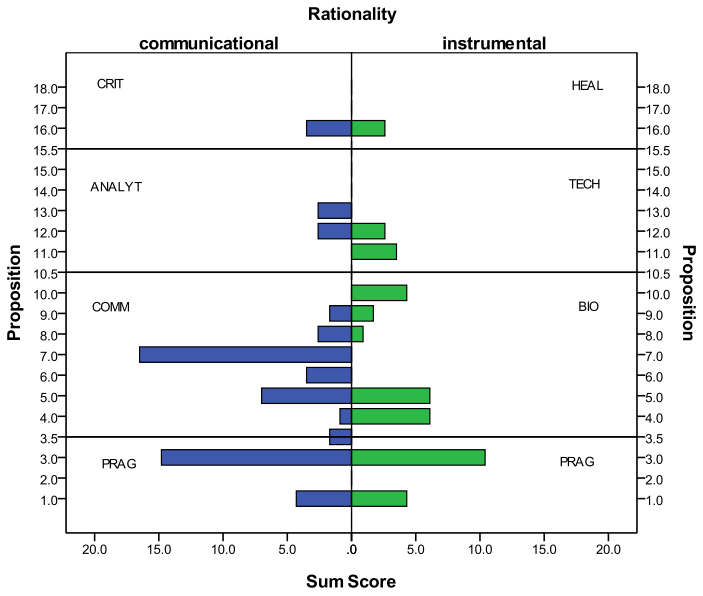
The communitarian approach deals with the issue of risks in a more direct way. As explained before, committee members holding this approach argue that uncertainty can never be circumvented or tamed in clinical research. Therefore, the idea of calculation cannot be invoked. Deeply concerned with local and concrete factors, the communitarian approach rejects the abstract stance proposed by the risk-benefit perspective.

One of my interviewees voiced a vast range of communitarian concerns, as the following *discourse graphic*[46] shows:

[46] The construction of *discourse graphics* is explained in Chapter 2.

Figure 4.3 – Discourse graphic n. 5

(Cape Town/C7/Social scientist/08-11)



Here, as is normal in the communitarian mentality, pragmatic claims have an important weight. This interviewee's discourse is deeply marked by a communitarian view of ethics committees (claim COMM7). At a certain point of this interview, having felt the presence of strong communitarian concerns, I asked him a question aimed to "test" his communitarian stance, and this is the answer I was given:

> "*Do you agree that any type of research involves a certain amount of harm?*
> I think any type of research involves the risk of harm. I also find that risk and harm get confused all the time. You know, people say: 'Are there risks in the research?' You know, risk is just a chance [...] Other thing is saying: 'Are there harms in this research?' A harm is an event. I can't tell you if the research was harmful until the research is finished and you can see if you've had the event. So the risk is the probability and the harm is the event. So I think that any research process, because it involves people doing that, interacting, being out in the world, you know, somehow engaging, then there is always some kind of (even if it is unattended), you know, some kind of harm that is possible [...]."

This distinction could not be more instructive for our purposes here. *Risks* would be the predictable, manageable, calculable terms (or "probabilities") assumed by the bioethical mentality whereas *harms* would be the uncertain phenomena (or "events") that haunt the communitarian mentality. According to Hacking (1990, p. 96), French mathematician and physicist Poisson made a distinction that has some similarities to the one advanced in the previous quote: "probability" is the force of the evidence we have to affirm that a certain event will take place, while "chance" is a concrete feature of the event, its tendency to occur.

Mazur (1985) also talked about two different mindsets. On the one hand, there is the risk-benefit perspective, as explained before. On the other, there is an attitude that refuses these trade-offs by claiming that some goods are so precious that they cannot be balanced against bads. Driven to its highest levels, this second mindset can turn into a "humanist perspective." "In essence, it says that one cannot appraise qualities as diverse as beauty, human life, and industrial profit in any common currency, and to even attempt such comparisons degrades the human condition" (Mazur, 1985, p. 27). The communitarian mentality certainly frames qualities such as human life, particularity and originality as fragile resources that need to be protected from commensurations. Here, affects come to play, being particularly effective because they make calculations of pros and cons become redundant (Finucane et al., 2000).

As a consequence of these ideological differences, there is disagreement in the ways in which our two mentalities frame the globalization of trials, an issue that is explored in the following section.

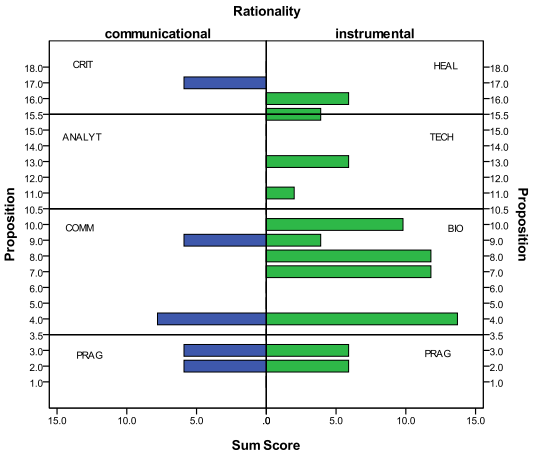
4.2.4 Global trials from a bioethical and communitarian viewpoint

The following *discourse graphic,* depicting a bioethical discourse, derives from an interview conducted in Cape Town:

This committee member has a background in social sciences and became gradually interested in bioethics, on which she did her postgraduate studies. Generally, bioethical discourses do not display such high scores in terms of pragmatic claims. Another exceptional feature, here, is the presence of a relatively important score in a critical claim (CRIT17). In spite of these characteristics, this discourse can certainly be seen as expressing the bioethical mentality. As the graphic shows, the main claim is BIO4, which stresses precisely the risk-benefit ratio in clinical research.

Figure 4.4 – Discourse graphic n. 14

(Cape Town/C7/Bioethicist/07-11)



Calculations pertaining to risks and benefits are also the main ideological tool with which the bioethical mentality frames the globalization of clinical trials and the operations of multinational companies. Therefore, every country should balance the goods and bads implied by clinical studies. The same interviewee gave me the following explanation.

> "*So maybe this balance between benefits and risks is more complicated in clinical trials [than in academic studies] and especially international trials.*
> Yeah. Yeah. Inevitably (I think the same with Brazil), the benefit is going to the developed world, without a doubt, and particularly to the US. Often, they're doing the trial purely so that they can be registered with the FDA; they're needing the numbers. But, equally, your researchers argue that it does expose them to international research. They do use some of the money that they are given from the trials to improve the services that they are offering [...] It is an indirect benefit, again, but it does keep the researchers... It teaches good research methods, usually, although they haven't been involved in the design of the protocol [...] You know, they do learn to conduct research fairly thoroughly. So there is that side of the benefit equation [...]."
> (Cape Town/C7/Bioethicist/07-11)

The success of each *mentality* depends also on the possibility of applying their claims to global issues. In the previous quote, the interviewee used the idea of risks and benefits to frame global research. According to her, even though actors who are based in developed countries are more likely to reach their goals with global trials (risk), local researchers are "exposed to international research" and can therefore learn "good research methods" (benefit). From a bioethical point of view, the globalization of trials is seen as a moral equation asking for solution. Countries should only accept to take part in global studies if more benefits than risks can be gleaned. Eventually, every research protocol must be assessed individually so that committees verify where benefits and risks go to.

> "*Are you somehow concerned with the fact that today there are many protocols being conducted in several countries at the same time?*
> [...] I'm not concerned with the fact that there are different countries, as long as the populations... For instance, it is done in Germany, France, Brazil, United States... I'm not concerned about that. What does concern me is when they do it only in Brazil, when a new medicine, whose effects to research participants are unknown, is tested only in Brazil and not in Germany where the medicine comes from [...] Or when it is tested in India, Brazil and Peru. Why don't they test it in Switzerland, Germany, in the First World? Are we guinea pigs? [...] But when the study is multicentre and international, with all the countries facing the same risks and gleaning the same benefits, in order to know how the medicine works in different populations, that doesn't concern me so much [...]."
> (São Paulo/C1/Physician/04-11)

When focusing on these issues, the *communitarian mentality* tends to lead people to take very suspicious positions. Here, this mentality is decisively shaped by the remembrance of international relations considered as exploitative. Eventually, countries and regions are almost thought of as individuals. The strongest countries would be prone to inflict several types of sufferings on the weakest ones. The basic example is colonization, whose remembrance haunts the communitarian mentality, always renewing the image of colonies exploited and impoverished by colonizers. The field of medical care and research also belongs to this history. As Comaroff and

Commaroff (1992) showed, medical practices were used to discipline colonized groups, and African colonies were turned into huge medical laboratories.

The communitarian mentality also draws on recent, contemporary inequalities. For instance, the uneven global distribution of research activities and infrastructures can be emphasised (Busfield, 2003, Busfield, 2006). On this point, pragmatic concerns manage to permeate the communitarian approach quite efficiently. What could be viewed as opportunities for international partnerships (in a *technical* approach) ends up being the source of dire concerns.

> "*Do you think there is any type of protocol that deserves more attention from an ethics committee?*
> [...] I think things like, you know, how much you're going to... taking blood. I think those issues. I would be concerned about making available... I have concerns about, you know... I know open access is a good thing but making available, you know, all the biological material from South Africa into, you know, the hands of the first world... You know, we just don't have the same access and skills [...]."
> (Cape Town/C7/Anthropologist/07-11)

> "*Are you somehow concerned about the fact that today there are many foreign companies conducting clinical trials in South Africa?*
> Yes, I do... because I just have the idea that they think this is a population, in Africa (I'm not only talking about South Africa but in Africa) it is a population that they can come in, do a trial and go out. Sometimes I'm worried about: what about afterwards? Don't they make that drug available to that... to the participants in the trial that they have done in a particular country? [...] those are the things I'm concerned about, that they are multinational companies, they perhaps don't think of the people they leave behind when they've done their trials."
> (Cape Town/C6/Nurse/08-11)

Therefore, global clinical research, and especially protocols sponsored by the pharmaceutical industry, is seen as one of the causes and consequences of global inequalities. In the communitarian mentality, globalization is framed as an endless source of inequalities and exploitation. Hence, the need for voicing claims such as the

one made by Epstein (2007, p. 199): “For the most part [...], rich Western countries will be reaping the benefits of the substantial and growing corpus of research now being conducted on the bodies of the global poor.”

For those who firmly subscribe to communitarian views, international research efforts can eventually be seen as sources of several imbalances. In a sense, global inequalities would impair the application of concepts and procedures formulated in rich countries to the reality of poor countries. As Hauser and Johnston (2011, p. A8) claim: “Another issue relates to uncertain generalizability of findings from global trials, due to differences between the population studied in the developing world and the target population, usually in the developed world.”

> “[...] we have had clinical trials, particularly (it must be similar for Brazil) where clinical trials are structured for the developed world to be rolled out in the developing world and the criteria that they’re using for admission to the trial are maybe criteria that are relevant in the developed world but it is prejudicial or racialist or discriminatory in the developing world [...].”
> (Cape Town/C7/Social scientist/07-11)

International differences are stressed in this way because, as we have seen, the communitarian approach focuses on concrete factors, whether they are personal or national.

Once again, it is important to take into account the *conversations* between the communitarian and bioethical mentalities, which can be combined almost freely. In the next quote, I broke one interviewee’s reply into different composing parts:

Question	"*Do you think there is some kind of protocol that deserves more attention from an ethics committee?*
Bioethical/Communitarian	Hmmm... [Pause.] You know, we imagine diseases... For instance, like HIV-Aids [...] I think we need to pay attention to vulnerable populations. If someone would like to do a trial in prisoners, we say: 'Why prisoners? And why prisoners only?' So you have to look whether there is small coercion.
Communitarian	Remember, South Africa, most of the participants are... in our experience, they are black people. Most of the researchers are white people.
Bioethical	How do they obtain consent? Do they use interpreters? Do these people understand? I mean, medical students don't understand some of the informed consents that are submitted, so imagine for an ordinary person [...]." (Pretoria/C8/Pharmacist/07-11)

Therefore, the more advanced the globalization of clinical trials, the bigger the number of issues to be coped with by these two mentalities. One might suppose that the global diffusion of codes and guidelines pertaining to clinical research could appease the situation. However, as claimed subsequently, regulations themselves are the basis for new agreements and disagreements between mentalities.

4.2.5 Views about regulations

Committee members holding the bioethical approach hasten to talk about regulations, guidelines and codes as fundamental tools, which render clinical trials safe and sound. For some interviewees, references to national and international regulations punctuated the whole discourse, as in the following examples.

> "*In your opinion, what is the main goal of an ethics committee?*
> One main goal, protect the integrity of the patients. And everything else around it... And it is in principle linked to these guidelines which are called Good Clinical Practices (GCP). And GCP guidelines have two objectives and that is... You know about GCP? [...] the ethics committees base their opinions, actually, on GCP, on Declaration of Helsinki or whatever law, to make sure that all these requirements are met [...]."
> (Cape Town/C6/Pharmacologist/08-11)

When you first came to the committee, did you know the work of the committee, did you...

No, I hadn't seen a protocol in my life before. And in those days, the application forms were so detailed and I used to look out for things such as [the Declaration of] Helsinki, IBPI,[47] insurance, payouts and that sort of thing. Today most of that is taken care in the application form. So I used to sort of... I was a Helsinki specialist. Every time a protocol came up and the Helsinki wasn't mentioned, I put my hand up [in the committee meeting] and said: 'Helsinki!' And the [committee] chair then knew exactly that it wasn't [...] Do you know what Helsinki is?"

(Cape Town/C7/Lay member/05-11)

On this point, the Brazilian situation is particularly interesting. In 1996 the country published its first guidelines on clinical research with human beings, the so-called Resolution 196, which also created the National Commission for Research Ethics (Conep). Therefore, the Brazilian system review became organized around two main bodies: ethics committees, responsible for the local review of projects, and Conep, which oversees the national system and reviews some protocols. At that time, the Brazilian Society of Bioethics managed to have a strong influence upon the process, making the Resolution be decisively shaped by bioethical principles. In my interviews in Brazil, people holding a bioethical approach mentioned, almost proudly, the importance and the binding presence of the Resolution.

"One last comment! We talk a lot about difficulties, don't we? But we have to recognize the big advancements that it was possible to make. We've advanced in the research quality. That is evident to me. The research that was done in the 1990s, at the beginning of the 1990s [...] is not comparable to the research that is done in 2011, in terms of quality, and much is due to the system [...] the CEP-Conep system helped us very much. A big contribution, among others, is that nowadays people talk about research ethics [...]."

(São Paulo/C4/Bioethicist/05-11)

[47] Intrabiotics Pharmaceuticals (IBPI) is a private company that runs some clinical trials. The interviewee has probably read an ethical manual prepared by the company.

> "*I have always thought: Oh, there must be a moment in the review that the reviewer may get stuck due to a lack of scientific, technical or juridical knowledge.*
> [Pause.] In the Resolution 196 (which is very clear), protocols must be assessed from an ethical or bioethical point of view by any person, including those from the community. So the protocol's structure must be clear, so that the person is able to read it [...] The person who assesses the project must know and understand what is being proposed by the project, and whether the project benefits the patient or not. Hmmm, I cannot tell you what is the paragraph of the resolution 196, but it is very precise [...]."
> (São Paulo/C2/Nurse/04-11)

Thus, the CEP-Conep system, and especially the Resolution 196, has become fundamental principles for committee members holding the bioethical mentality. Particularly telling is the history of a Brazilian person who spontaneously joined her committee. In her first visit to the committee, she was given the Resolution 196 to read and become familiar with the bioethical universe.

In some of its aspects, the bioethical mentality share similarities with juridical thought. In the next section, it is shown that general principles are decisive for this mentality. In this way, there tends to emerge a sort of juridical logic, based on general rules. As Bosk and Frader (1998, p. 114) explain:

> "[…] once structural problems have been turned into ethical problems, there is a social tendency to turn them into legal ones. This move places an emphasis on contending parties, formal rules of procedure [...], and then justifications for action in terms of principles. The emphasis here becomes not just this case but all cases that could arise in the future and would be like this case."

Not surprisingly, then, the bioethical approach can emerge, and assume practically the same features, in different cities. By the same token, it is not surprising that the globalization of guidelines on clinical research is warmly welcomed by the holders of this mentality.

Actually, an ethics committee could also be framed as a sort of jury, which would be responsible for applying "bioethical laws," arranging preventions and

reparations. As showed by some authors, committees have been considered as bodies having the ability to prevent disputes from going to courts (Rothman, 1991, Bosk and Frader, 1998, p. 97). Thus, some people seem to assume that committees are supposed to make a sort of early justice, hampering legal troubles before they take place. If there is a symbolic role played by committees, this is represented by the idea of justice being made through the review and conduct of clinical trials.[48]

Committee members embracing the *communitarian mentality* tend to mention regulations and standards much less frequently. Of course, such references can also happen, for as claimed before, moments in which the communitarian and bioethical approaches converse are not rare. However, those people seem to presuppose "[...] the unpredictability inherent in experimental work even in the relatively regulated and standardised form of the randomised controlled clinical trial" (Will and Moreira, 2010, p. 8).

This does not mean that the communitarian mentality lacks any kind of juridical sense. However, the inspiring idea, here, would be that of natural rights of men. The French revolution, which discovered compassion as a social force, was also responsible for stating, in the Declaration of the Rights of Man, the binding presence of natural rights common to all human beings. Based on this idea, the society that emerged from revolution "[...] was supposed to rest upon man's natural rights, upon his rights insofar as he is nothing but a natural being, upon his right to 'food, dress, and the reproduction of the species,' that is, upon his right to the necessities of life" (Arendt, 1963, p. 63). In clinical research, these types of rights can be quickly identified, especially by committee members who are concerned with health care and the research subjects' physical integrity.

Differently from the bioethical mentality, the communitarian mentality does not consider international regulations as satisfactory safeguards for the so-called vulnerable populations and countries. On the contrary, regulatory frameworks are said to reflect international inequalities. In this way, poor countries would hold fragile regulations that cannot hamper abuses in clinical research. For example, Angell, whose studies on pharma companies and clinical trials is strongly marked by communitarian

[48] In my statistical analyses, bioethicists and layers were grouped together because of two reasons: the ideological similarities between bioethics and the juridical thought, as explained here; and the fact that, in my fieldwork, bioethicists and layers tended to express similar views.

concerns, compared the United States regulations with those of poor countries, reaching the following conclusion:

> "Research in the Third World looks relatively attractive as it becomes better funded and regulations at home become more restrictive. Despite the existence of codes requiring that human subjects receive at least the same protection abroad as at home [United States], they are still honored partly in the breach. The fact remains that many studies are done in the Third World that simply could not be done in the countries sponsoring the work" (Angell, 1997, p. 848).

Four of my interviewees echoed this concern.

> "*[...] Over the last years, there has been a big expansion of clinical trials in countries like South Africa and Brazil. Do you think that this growing number of protocols is really important and necessary?*
> [...] I think some of the growth in places like South Africa, Brazil or other places is that drug companies are finding it harder to do work in Europe and the US, because of the regulatory systems there, and it is easier to get it done here. This is also not a good reason, you know, to be doing it here, but that is part of it [...]."
> (Cape Town/C7/Anthropologist/08-11)

This concern with international inequalities is decisively informed by another basic feature of the communitarian approach: its attempt to identify and protect particularities.

4.2.6 Between principles and particularities

As claimed before, the *instrumental rationality* (to which the bioethical approach belongs) helps to realize the ideal of commensurability, according to which different qualities are reduced to comparable aspects. On the other hand, the *communicational rationality* (to which the communitarian approach belongs) foregrounds particularities. This division cannot be manifested in the *pragmatic*

mentality, which is composed by very basic claims and concerns. Nevertheless, as soon as one tries to voice controversial, debatable claims, and therefore bring the discourse to the level of *foreground knowledge*, the distinction between commensuration and particularity begins to become clear.

On this point, the communitarian mentality shows its emphatic dimension. Indeed, people holding the communitarian approach seem to be strongly distressed by any kind of enterprise through which local, national, personal or social specificities are despised. The frequent use of principles by the bioethical approach sounds particularly annoying. Hence, some claims such as: "Impartial moral reasoning [...] appears unable to uphold ideals of respect for persons, and at times their communities, and social equality for potential participants of research and intended beneficiaries" (Eckenwiler, 2001, p. 49).

For committee members, such concerns emerge in the form of claims stressing particular national problems. In South Africa, for instance, the huge population of people infected with HIV, as well as racial differences, are issues generally commented with a communitarian vein.

> "*Over the last years, there has been a big expansion of international clinical trials in countries like South Africa.*
> Hm hm.
> *Do you think that this growing number of protocols is really important and necessary?*
> For South Africa? Yes. Because we have a big problem. If you think about HIV alone, the companies put a lot in HIV research coming out of this country [...] But this is the problem... Going back to vulnerable groups, you get over-researched. A lot of our groups are over-researched, because they set in there, they've got this disease and people say: 'Well! We can use them! We can use them!' [laughter] You know, when you take the number of participants in each trial and then you add... Add up all the participants in only HIV trials, you probably get half of the population! They've got to make sure that you don't get the same person doing three, four trials.
> *Yeah, 'cause HIV trials are huge!*
> Usually, they take thousands of people and every time they go, it is 150 Rand or whatever it is. You can make a living out of it, but you have to take all those different drugs, which is not so good [laughter]. That is why they're vulnerable."
> (Cape Town/C7/Lay member/05-11)

"*Over the last years, there has been a big expansion in clinical protocols in countries like Brazil and South Africa. Do you think this big number of protocols is really necessary and important?*

[...] It is... As long as people are skilled in carrying out clinical trials... The only problem in South Africa, 90% of participants are black but 90% of researchers are white, and I don't understand why more and more black people are not being recruited to participate in clinical research. I don't...

Black doctors.

Yes, black doctors."

(Pretoria/C8/Pharmacist/07-11)

In the three South-African committees I studied, the vast majority of members could be considered as white people.[49] Of my 17 South African interviewees, only three members could be visually considered as black. All these three interviewees spontaneously declared themselves as black and trumpeted complaints about racial differences in clinical trials in the country.

On this point, the content of compassion that fills the communitarian mentality reappears, leading people to voice concerns with socially disadvantaged groups. Thus, clinical trials would be further institutionalizing social problems. This is the stance informing, for instance, the claim made by Lakoff (2005, p. 32-33), according to which the medicalized and institutionalized approach to psychiatric patients transforms "an individual experience of suffering" into a general, impersonal case. We are once again dealing with an emotive content that since the times of the French Revolution, have subjected people to "the boundlessness of their sentiments" (Arendt, 1963, p. 84-85).

Therefore, the communitarian approach is constantly disrupted by medical and statistical enterprises, which gathered their forces in order to build up an abstract and impersonal view of the human body. Epstein described this view, claiming that it has disregarded specificities for the sake of a general explanation in which the white male individual has often been taken as the model of human being.

[49] I attended meetings in all these committees.

> "A crucial stage in the standardization of the patient, the quantification of medical research, and the increased reliance on the human subject as an experimental object was the emergence of the randomized, controlled clinical trial as a distinctive kind of medical experiment" (Epstein, 2007, p. 48).

Still according to Epstein, randomization abolishes particularities by turning subjects into hollow clinical cases, while turning researchers into "blind" followers of a protocol.

In the bioethical mentality, however, the existence of general concepts does not seem to cause major ideological disturbances. On the contrary, it is frequently in tune with the use of principles that is typical to this approach. Here, committee members tend to be seen as representatives of professional groups. In this way, an ethics committee would be what results from the combination of different expertises.

> "*And do you think that nowadays ethics committees are well-equipped to protect people?*
> Well... I mean, if you look at the way that this ethics committee has been composed... Our chairperson is a medical doctor [...] And also the lady who presented the protocols. There are two medical doctors. The guy that sat on your right [during the meeting[50]] is a pharmacist [...] So there is enough medical knowledge. This girl who were sitting here, she looks at protocols from a psychology point. This lady that was sitting here, she is a legal person, and so is other person. Two legal people. This guy is a layperson and the lady here is a layperson [...] So we are able to look for the problems that might pop up. I mean, where there can be transgressions? There can be transgressions in medicine, in the study design, in the legal rights of your patients... So we, hopefully, intercept with all of that [...]."
> (Pretoria/C8/Bioscientist/07-11)

Hence, some people consider that "[...] in order to effectively review protocols, ERCs [ethics research committees] should be composed of members of diverse backgrounds [...]" (Nyika et al., 2009, p. 192). From this viewpoint, members are representing their expertise area, as well as representing themselves as rational

[50] This interview happened right after the committee meeting.

thinkers in the Kantian sense of the word. According to Rothman (1991), the bioethical model avoids individual deliberations and takes collective decisions as a moral template. Consequently, the bioethical mentality appreciates the idea of consensus, which is precisely the situation in which different autonomous individuals come to make their judgements coincide. When this coincidence comes to play, a sort of mighty and impersonal will emerges, imposing itself over the individual wills.

> "So the main idea [in a meeting] is to reach consensus. The review is subjective, but the committee's decisions are taken by several people, so this subjectivity should be diluted and many times corrected, so that the decision can really be collective and not personal."
> (Brasília/C4/Pharmacist/04-11)

As Arendt explains, a distinction was drawn in the seventeenth century between two models of social contract. "One was concluded between individual persons and supposedly gave birth to society; the other was concluded between a people and its ruler and supposedly resulted in legitimate government" (Arendt, 1963, p. 169). The bioethical mentality is inspired by the second type of contract. The "governor," to which members have to transfer their "power," is the committee's will. Thus, even though everybody is free to voice views and opinions, everybody has also to comply with the decisions taken by the group. Hence, some (apparently) paradoxical statements such as the one voiced by one interviewee:

> "Sometimes there are people who agree or disagree, there is debate and there is consensus. And when there is consensus, this consensus is followed even though some people still disagree [...]."
> (São Paulo/C1/Physician/04-11)

Eventually, the obstinate search for consensus can create a false sense of democracy and legitimize a model that can systematically ignore divergent views. It is possible to argue that in ethics committees, the *bioethical* and *technical mentalities* always tend to prevail (for reasons that I try to clarify all over this thesis). This techno-

bioethical approach ends up forming this abstract "Ruler" with which other mentalities have to compromise and or struggle.

The bioethical discourse often stresses broad ideas such as autonomy and justice, drawing less attention to social contexts (Kohlen, 2009, Bosk, 1999/2008). In 1978 the so-called Belmont Report was issued, proposing that research should be based on the principles of respect, beneficence and justice. Since then, many people look at clinical research through the lenses of these and other principles, in an attitude that was called "principlism" (Bosk, 1999/2008). Eventually, principlism would instil a model of thought in which "[...] there is a single, correct solution for each ethical problem, which is largely independent of person, place, or time" (Bosk, 1999/2008, p. 15-16). When this stance becomes very fierce, the final discourse may sound quite cold and bureaucratic:

> "*When you're reading a protocol, do you somehow think about the people who are going to take part in the study?*
>
> In which sense?
>
> [Pause.] *Hm... Er... Actually, I'm asking this question to know to which extent... After having read several protocols, as you have, to which extent patients end up becoming something abstract and barely concrete.*
>
> But they are abstract [...] Aren't they? [Laughter.] Essentially, they are abstract [...] For the researcher, they are not abstract, but for those who assess [the study], they are certainly abstract. Not only for those who assess the protocol but also for those who assess articles, for those who assess anything related to the study and don't deal with patients. So I think this is where there is a fundamental difference, which doesn't mean that you're not going to defend ethical principles in the procedures within that protocol. But you defend ethical principles abstractly... of course. Conceptually. It is not something practical [...] That is why it is abstract [laughter].
>
> *[Laughter.] And don't you think that an ethics committee has any type of duty or responsibility toward the patients?*
>
> It has a responsibility toward the protocol [...] It is the researcher who has the responsibility toward the patients.
>
> *And what does it mean to have a responsibility in relation to the protocol?*

It is to approve the protocol by observing the adequate principles, whether they are scientific or ethical."

(São Paulo/C3/Physician/04-11)

This example of pure bioethical/technical discourse is rare, for bioethical claims are generally accompanied and tempered by the communitarian approach and its contextual concerns. Nevertheless, the bioethical mentality does strive to look at clinical trials through the lenses of general principles.

"*Today, what is your main motivation in your work in the committee?*

Protecting research subjects [...] I get technical underpinning from Resolution 196, verify whether the project is in tune with Resolution 196, with the principles of beneficence, nonmaleficence and justice, and if it is not in line with this ethical analysis, I refuse it [...]."

(São Paulo/C2/Nurse/04-11)

Principlism has an ideological corollary: if the same principles can be applied everywhere, then the review of clinical protocols depends not so much on personal talents but on the acquisition of techniques and skills. Eventually, a good committee member would be someone who has undergone appropriate bioethical training. In its turn, the communitarian mentality stresses subjective, concrete factors shaping the committee's work (such as time available for reading research projects) and relies much more heavily on personal relations and help between members than on written documents. The following quotes compare these stances.

Communitarian	Bioethical
"*This [debate about the use of placebos] is something that seems to have no solution, doesn't it? We can't know where it goes.* Actually, if we evaluate this question here, there will be a certain view, a group will see it in a certain way, in Joinville[51] there will be another view, in London there will be another view. As we are talking about human beings, groups are very particular and will look at it with different eyes, different notions, different personal life histories. So the view will vary according to the group that evaluates that question, you know. *So there is a subjective and even regional dimension in the assessment of a protocol.* A very strong dimension. Yes." (Brasília/C4/Microbiologist/04-11)	"*[...] Let's imagine that I am going to work as a committee member, in a private committee. What is the advice you would give me so that I can be a good committee member?* Ah... I think your first thing that is really important is basic training in how to review protocols... Okay, first you have to start a basic training in the philosophy of ethics, research ethics [...] And, I think, once you've got that behind you, learning how to review protocols and how to review informed consent documents is very important. You know, what do we look at? What is important? You know, you look at it from an ethical and a scientific perspective [...] once you've got the training behind you [...], you can pretty much take any kind of proposal, whether it is... whatever the indication is. And from an ethical perspective, you can say, you know, this is okay or it is not [...]." (Cape Town/C7/Committee Director/08-11)
"*Okay. Let's imagine that I am going to start working in an ethics committee. What is the advice you would give me for me to be a good ethics committee member?* Well, many things [...] You have to learn to hear but you have to learn to speak as well. Only hearing is not good. What else? You have to focus very precisely on what you have to analyze. If you don't know it, don't analyze, ask for help, ask for support from someone because there is always someone who knows it, because, as you see, there are specialists from several areas here [in the committee]. There is someone who knows it [...] If you have time available and like what you do, you don't have to think twice. You have to dedicate yourself indeed." (São Paulo/C3/Lay member/05-11)	"*Let's imagine that I'm going to be a member of this committee. What would be the advice that you would give me so that I can be a good committee member?* Well, we've got a specific training program that takes two afternoons where we give you all the information [...] We've got a booklet that we hand out and say: 'This is what is expected of the reviewers, this is what you specifically look for [...]' *But is there any advice that you would give me at the personal level?* Ah... [Pause.] I don't think anything specifically... I think most of the concerns would be addressed in our normal working procedures etcetera etcetera [...]." (Cape Town/C6/Physician/08-11)

Whereas holders of the bioethical view stress the importance of technical and theoretical training, holders of the communitarian approach focus on personal relations within the committee and are suspicious about universal assessments.

[51] Joinville is a city in the South of Brazil.

Obviously, these discordances lead to different ways in which people frame ethics committees and speak of their own activities as ethical reviewers.

4.2.7 Bioethical and or communitarian committees

According to the two mentalities described in this chapter, what would be the definition and duties of both ethics committees and committee members? Basically, the communitarian mentality leads people to frame committees as part and representative of the surrounding community, which can be thought of as the scientific community in which the committee operates, a region or the whole country. In the bioethical mentality, committees are seen as a sort of moral calculator, applying general principles to particular cases.

Communitarian	Bioethical
"[...] I have been in this committee for eight years, I have studied a lot of protocols, I've learnt a lot about science [...] but I *don't*... I *do not* read protocols from the point of view that I know anything about science [...] I look for the things that the man on the street would look for when he reads a consent form or reads an information sheet. I look at it from his point of view." (Cape Town/C7/Lay member/05-11)	"*So in your opinion, what is the goal of the committee?* Evaluate the beneficence, the nonmaleficence and theeeeeee..... The beneficence, the nonmaleficence and... [pause] and the legality of research [...] I've forgotten the other word. There is another word. I've forgotten it. So I mean, that is what you evaluate in an ethics committee [...] To which extent there are benefits, from which point it is harmful or brings about harms rather than benefits, and the justice, whether the project is just [...]." (São Paulo/C2/Nurse/04-11)
"*When you're analyzing a project, do you somehow think about the participants, about the people who are going to join it?* Yes, I do. As I told you, when I read an informed consent form, or when I read the description of what is going to be done, I always imagine my father, my mother, myself, joining that study, whether I would appreciate that. And when I read the form, I look at the protections that are offered to people in the case they have any damage, in the case things don't go as expected. Adverse events do happen and are sometimes unattended [...]." (São Paulo/C1/Physician/04-11)	"*In your opinion, what is the main goal of an ethics committee?* One main goal, protect the integrity of the patients. And everything else around it... And it is in principle linked to these guidelines which are called Good Clinical Practices (GCP). And GCP guidelines have two objectives and that is... You know about GCP? [...]" (Cape Town/C6/Bioscientist/08-11)

Therefore, the bioethical mentality tends to have a procedural view whereas the communitarian mentality frames ethics committees from a personal and social perspective. As one of my interviewees put it: “Don’t just do the trial and leave the community just like that.” This sentence was voiced in Cape Town by a nurse whose discourse turned out to be dominated by communitarian claims. When she joined the committee in 1993, still in the apartheid era, she felt insecure and ashamed because she was the only “female,” “coloured” member, to use her terms. Afterwards, however, she perceived to have a role to play. In the following quotes and their respective *discourse graphics,* I am contrasting this nurse’s claim with a claim voiced by a Brazilian committee member:

Communitarian	Bioethical
“As I grew into this work, I realized: ‘But I’m the one talking for the patient here, or the participant, because people would talk about the scientific things and forget about the patient, you know. So at that time I could see what my role was [laughter].”	“*Do you think these people [committee members] who are working on a voluntary basis should earn something?* No [...] in theory, ideologically and philosophically speaking, this is something that should be voluntary, I don’t see why we would be remunerated if this is a bioethical advisory, let’s say, that we provide, you know [...].”

Figure 4.5 – Discourse graphic n. 15

(Cape Town/C6/Nurse/08-11)

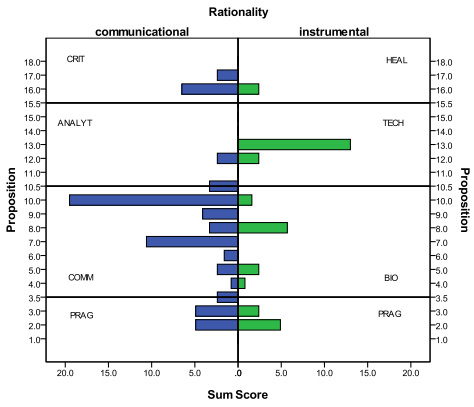
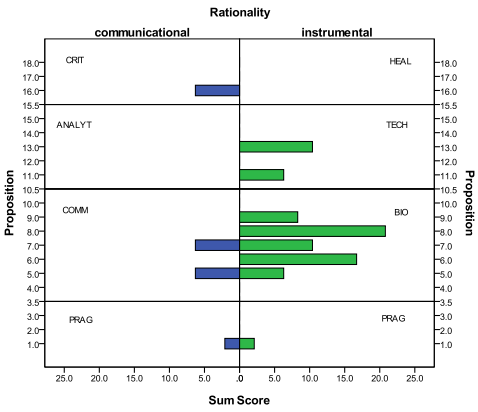


Figure 4.6 – Discourse graphic n.26

(São Paulo/C1/Bioethicist/02-11)



As these *discourse graphics* show, pragmatic claims tend to be more important in the communitarian mentality. For the bioethicist, the major concern is the provision of information to participants, who should be let free to decide about their participation (claim BIO8). The nurse affirms to be particularly concerned with participation of poor people, less educated subjects and children in trials (COMM10). It is interesting to note the coherence of the nurse's discourse, who voices all possible claims from PRAG2 to ANALYT10.5, denoting a smooth passage from *background* to *foreground* knowledge. As the quote above suggests, she began to feel at ease as a committee member in the precise moment when she "discovered" the communitarian approach. By representing subjects, she could somehow balance the weight of the physicians' scientific knowledge. Sometimes, the communitarian mentality appears as a sort of "ideological revenge," for the committee members who feel to be the most prepared to represent the community are the ones who lack a medical and scientific background.

From this communitarian point of view, belonging to an ethics committee fosters the feeling of local or national relatedness. Some committee members are eager to claim that they are in fact carrying out a service for their institutions or places.

> "*Nowadays, what is your main motivation to work in the committee?*
> [...] I think it is maybe continuity. Sometimes I want to stop but I don't know, I think I contribute [...] I think today there might be two people to do what I do. So it would be too big a sacrifice for the hospital. And I like the hospital. It is the place where I studied, my friends are based here, I found opportunities... from here I was indicated to hold positions, to be the director... I mean, I can't avoid feeling the obligation to give something back."
> (São Paulo/C2/Physician/04-11)

> "*But do you consider it [the participation in the committee] as work?*
> No, I consider it as a communitarian contribution, so to say. I think each of us must give a bit of contribution in a voluntary service [...] To me it is a service I am always happy and proud to do [...]."
> (Porto Alegre/C5/Lawyer/05-11)

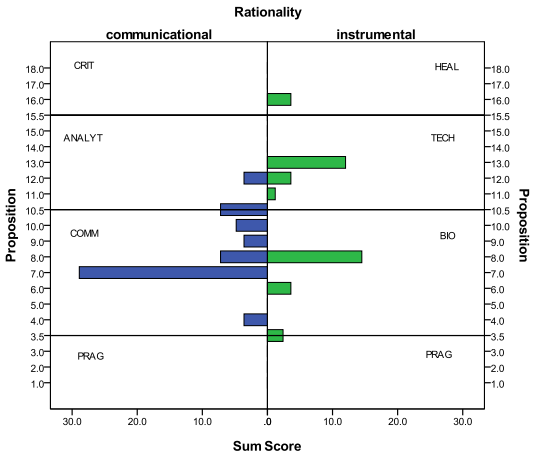
To be sure, these emotive and grand communitarian claims tend to flirt with religious (and more precisely, Christian) conceptions. According to Arendt, whenever social actors are motivated by strong sentiments, as was the case during the French Revolution, they start assuming that their good deeds should remain hidden. Extracted from the human heart (where it originally lies) and exposed in the public realm, the goodness of such deeds would be rapidly vitiated (Arendt, 1963). For committee members who embrace the communitarian mentality, the limited publicity of committees comes to be seen as a positive phenomenon, for they can therefore realize the communitarian ideal of being good community members while keeping their goodness protected and hidden. On this point, the following claim voiced by a lay member is very interesting:

> "*Today, what is your main motivation to continue to work in an ethics committee?*
> Look, it is what I say: I don't see myself not doing anything for the benefit of something [...] I need to do something for someone. I feel fulfilled... And I don't talk about it, I don't comment on it [...]."
> (São Paulo/C3/Lay member/05-11)

Thus, keeping silent about the deed, not mentioning it, seems to be considered as a pivotal aspect of the good action. This interviewee displayed strong communitarian concerns. Being retired and therefore having enough free time, she does, in addition to her participation in the committee, other services that she considers as "voluntary": she provides different sorts of help in two hospitals in São Paulo, and she often takes part in legal juries as lay member. This is the *discourse graphic* derived from her interview:

Figure 4.7 – Discourse graphic n. 25

(São Paulo/C3/Lay member/05-11)



Even though the weight of pragmatic claims is not important here (an atypical event for the communitarian mentality), the graphic does present some typical features of the communitarian approach, including an important conversation with bioethical claims. The claim she repeated the most frequently is precisely COMM7, which points out that committee members should look at research protocols from the subjects' viewpoint, protecting and representing the community.

Blending bioethical and communitarian claims is also possible when people talk about their views on ethics committees. In this way, a committee would be framed, for instance, as a body that protects the community by means of moral calculations. In order to show this phenomenon, I am cutting the answer given by one interviewee into different parts:

Question	"*Do you think that for those [members] who don't have a medical background, reading a protocol can be somehow more difficult? Can there be further difficulties?*
Communitarian	I think so. There are many technical terms that those who are not physicians will not understand, but I mean, for example... When you are here in this environment [the committee], you can ask a physician and so on [...] For me, the technical analysis, even though it is in cardiology or psychiatry, is easier. It is different for laypeople. And then, I think, what can they analyze, basically? The ethical part. Would I do... Would I agree to participate in this study? If I were this patient and were asked to take an injection, collect samples, have an anaesthetic to undergo a procedure, would I participate?
Bioethical	So I think this has to be the risk-benefit calculation for those who are not physicians, right? In addition: is it in line with the regulations? And something that is very important is the informed consent form [...]
Communitarian	You have to put yourself in the patient's position. Maybe, from this point of view, it is easier for laypeople than for me, being a physician [...]." (São Paulo/C1/Physician/04-11)

All the features, similarities and differences we have seen in this chapter have important social and political consequences. Indeed, the bioethical and communitarian mentalities frame committees and society in different ways. In the following section, these aspects are explored.

4.2.8 Political implications of the bioethical and communitarian mentalities

The bioethical mentality appears to be favoured by bioethicists, lawyers, physicians and bioscientists whereas the communitarian mentality tends to be particularly attractive for lay members, nurses, social workers and social scientists, as we can see in the following *discourse boxplots* derived from my 34 strong interviews*:*

Figure 4.8 – Communitarian mentality (South Africa and Brazil): discourse boxplots according to background

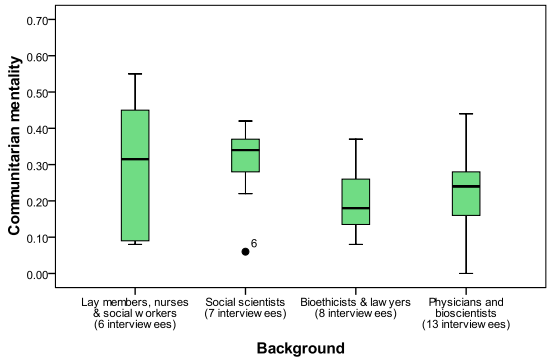
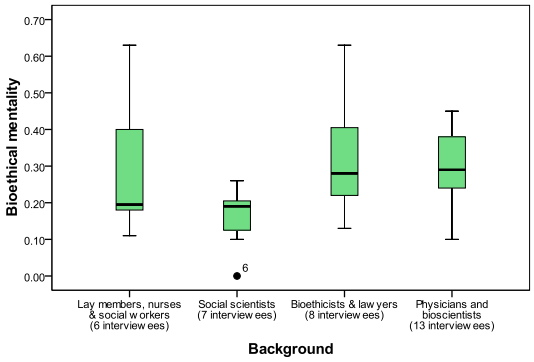


Figure 4.9 – Bioethical mentality (South Africa and Brazil): discourse boxplots according to background



We can analyse these graphics from three perspectives. Firstly, we can compare particular groups by moving from the communitarian to the bioethical mentality. Testing statistical differences between the two mentalities,[52] it was possible to verify a large difference for social scientists (p=0.001). Calculating the effect size statistic,[53] the result was of 0.84, a number that according to Cohen (1988), indicates a large shift. In other words, when choosing between bioethical and communitarian claims, social scientists seem to be strongly attracted by the latter. There is also a significant difference for physicians and bioscientists (p=0.04). Here, there is also a large shift (effect size statistic = 0.71) but in the opposite direction: these professionals seem to strongly favour bioethical claims. For other professionals, statistically significant differences were not verified.[54] These committee members seem to play with the *complementarity* between the mentalities without displaying particular preference for any of them.

Secondly, focusing on the *bioethical mentality* (Figure 4.9), we see that social scientists had the lowest scores, confirming the conclusion that they are not very likely to voice bioethical claims. Finally, focusing only on the *communitarian mentality* (Figure 4.8), the boxplots do not allow us to see differences clearly.

[52] I am assuming that for these mentalities, data are normally distributed. Therefore, I performed a parametric test (Paired-samples T Test).
[53] Eta squared.
[54] As explained in Chapter 2, my data are not powerful to identify statistical differences, because there is a small number of interviewees in each group.

Therefore, statistical analyses enable us to suggest two phenomena. First, physicians and bioscientists seem to foreground bioethical rather than communitarian claims. Second, for social scientists, the opposite tendency is verified. In effect, social scientists, for disciplinary reasons, stress contextual factors, a typical feature of the communitarian mentality. Moreover, it was argued that social scientists are particularly connected to the *background knowledge,*[55] another characteristic of the communitarian mentality.

As we have seen,[56] the bioethical mentality praises reviewing techniques. As a consequence, it is the approach that can be the most easily applied by ethics committees. In addition to offering principles that are supposed to underpin the committees' debates and assessments, it admits the presence of standardized procedures to review research projects. If nowadays ethics committees of many countries operate under more or less the same conditions, using similar application forms, consent forms and checklists, this is due, to a large extent, to a bioethical conception according to which clinical protocols, as well as their ethical review, can be commensurated and standardized. As Timmermans and Berg (2003, p. 64) explain, standards make it possible to cope with more complex tasks while simplifying the work undertaken by individuals, and therefore promoting a "partial delegation from worker to tool." Indeed, some of my interviewees declared to esteem the initial work undertaken by the committee's secretaries, who organize all the documents composing the research proposal and sometimes comment on the potentially problematic aspects of a protocol. By listening to the descriptions made by some interviewees, one might even have the impression of a machine-like ethical review of studies.

> "*Is reviewing a protocol an activity that takes you much time?*
>
> It depends entirely on the quality of the submission. Generally, low risk studies [...] would go quickly because we've designed our application form as such that there are quite a number of tick boxes, you know, the kind of crucial stuff. Does it comply with

[55] See Figure 3.3, page 99.
[56] Section 4.2.6.

Helsinki 2008? And they [members] sort of tick the box after seeing how they [researchers] are going to cope with confidentiality and anonymity [...]."
(Cape Town/C7/Bioethicist/07-11)

Certainly inspired by the memory of such tasks, some members seem to regret the automatisms of committees.

"This is the boring part of a committee. The committee has no intellectual bright or things like that. The committee is a... an automatic thing, an automatic working mechanism that must be almost repetitive. You're doing your post-graduate studies and you have to submit thirty documents. There must be someone to check your thirty documents, do you understand? [...] There is no need for new ideas. It is not a place for intellectual effervescence.
It is more routine than creativity.
It is routine. There is no creativity whatsoever [...]."
(São Paulo/C2/Physician/04-11)

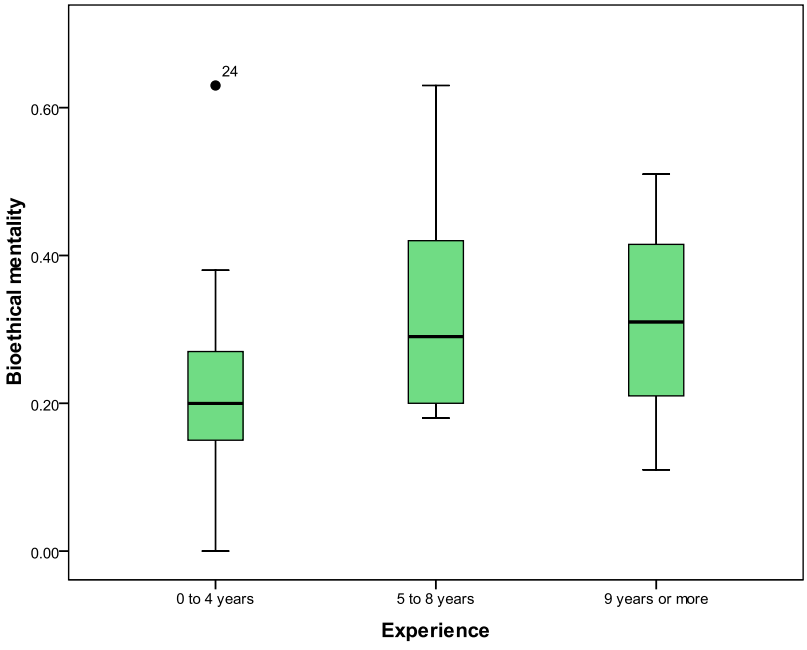
Nevertheless, standardized procedures provide committees with objective yardsticks, which can also be used in order to convey their "accuracy" or "productivity." According to one of my Brazilian interviewees, her committee considered for a while to obtain an ISO certification to attest the quality of its work. These procedures and bureaucratic processes also help signal the committee's concern with legitimate rules, even though this concern may remain at a purely formal level. As some authors showed, the maintenance of bureaucratic and formal structures, as symbols of legal compliance, is sometimes more effective, for the survival of an institution, than any actual compliance (Meyer and Rowan, 1977, Hawkins, 1984, Edelman, 1992).

Thanks to the procedural efficiency it supposes, but also to its symbolic operations, the bioethical mentality copes with dilemmas in a quite smooth way. For instance, the pragmatic approach introduces concerns pertaining to economic interests in clinical trials. The bioethical response to this question comes in the form of a new commensuration: every clinical trial proposed by the industry contains

comparable types of financial issues; therefore, it is possible to deal with them via standardized procedures. The next step is the preparation of economic forms and standardized budgets, with which committees can assess economic interests and verify whether they represent risks to research subjects or not.

Bioethical procedures, as well as bioethical notions, are most likely to be reinforced within committees in the years to come. Of 42 people interviewed in my fieldwork, 13 declared to have done courses or studies in bioethics or research ethics, from online courses to doctoral studies. It is known that some committees often ask specialists to give talks to their members. In the committees I studied, bioethicists and lawyers are the professionals the most frequently invited to provide such type of support.[57] As a consequence of these phenomena, committees have become promoters of the bioethical mentality. On this point, the following *discourse boxplots* (derived from 34 strong interviews) are very illustrative.

Figure 4.10 – Bioethical mentality:
scores according to years of experience in the committee[58]



[57] Also in Germany, hospital committees frequently invite bioethicists to give talks to their members. On this issue, see KOHLEN, H. 2009. *Conflicts of care: hospital ethics committees in the USA and Germany*, Frankfurt/New York, Campus Verlag.

[58] In Brazil, committee members generally have a four-year (renewable) stay in the committee. I adopted this division in these boxplots. In South Africa, members do not frequently have fixed stays.

These boxplots show that members who have been in committees for longer periods (9 years or more) voiced the biggest proportions of bioethical claims in their discourses. From the first to the third group, the median passes from 0.20 (members with 0 to 4 years in the committee), through 0.29 (5 to 8 years), to 0.31 (9 years or more). Only one interviewee, indicated as a dot (number 24) did not follow this pattern. This is a Brazilian nurse who has been in the committee for four years and voiced a very high level of bioethical claims in his interview. No statistically significant difference was identified for these boxplots but if we exclude this interviewee from the calculation, the difference appears (p=0.03).[59] Interestingly, by performing a post-hoc test,[60] it was seen that the difference lies between the first and second groups. Thus, it seems that by staying more than four years in an ethics committee, members can be permeated by an important range of bioethical concerns. For the group of old members (9 years or more), there is actually a slight reduction in the average of bioethical scores, signalizing the acquisition of other types of concerns (especially *analytical* and *critical* ones).

We can also analyze these data in terms of correlation. Considering all my 34 strong interviews and performing a statistical test,[61] it was verified a positive correlation of 0.36 between the level of pragmatic claims and the experience in the committee.[62] According to Cohen (1988), this indicates a medium correlation. Thus whenever the committee member goes from one group to another, the proportion of bioethical claims increases at a medium rate. The coefficient of determination is of 0.12, meaning that 12% of the increase in bioethical claims is explained by the increase in the years of experience.

These findings further support my argument that committees have become bioethical schools, so to say. Old members, due to their long exposure to the bioethical environment of committees, have this sort of claims deeply embedded in their discourses.

[59] I performed the One-Way ANOVA test.
[60] Tukey test.
[61] Spearman correlation.
[62] The p value is of 0.03.

In many situations, people join an ethics committee without having clear knowledge about the committee's procedures and responsibilities. In this way, an ethics committee will always appear, for those who are newcomers, a less bewildering universe when there are ready-made yardsticks, targets, written formulas and guiding principles to help members, a task that can certainly be more easily fulfilled by the bioethical than the communitarian mentality.

In addition, the bioethical view has undergone a well-known process of institutionalization over the last decades, assuming a "dominant position" in the field of medicine (Bosk, 1999/2008, p. 4). Many countries have witnessed the creation of societies, groups and committees whose main purpose is to deal with medical problems by handling bioethical principles and sometimes taking decisions (Guillemin, 1998, Bosk, 2002). As said before, the formulation of the 1996 Brazilian Resolution 196 was decisively influenced by the Brazilian Society of Bioethics, described as the "embryo of the Resolution" by an interviewee who participated in that process as member of this Society.

As a consequence of this strong position acquired by the bioethical mentality, some committee members claim that bioethical operations and calculations must be applied not only to clinical research but to every human activity.

> "*But do you think that if they [committee members] got paid, the payment would compromise their work... somehow?*
>
> [...] It doesn't seem right to have to be paid to be on an ethics committee. Ethics is high above anything else. You know what I mean?
>
> *No [laughter.]*
>
> Ethics... Ethics is supreme, a sort of... not god, but it is a very high part of research. It is the number one thing. It is the basis. The basis of the research is the ethics. No matter what you're doing, you're looking at the ethics. Everything has to go through ethics. So ethics is the basis of... it is the standard [...] It is like being the government. I'm not saying that the government in this country doesn't get over-paid [laughter]. Probably in Brazil too.
>
> *Yeah. [Laughter.]*"
>
> (Cape Town/C7/Lay member/05-11)

As a result of such grand conception, the bioethical approach, as well as the ethics committee model, is expected to conquer any kind of activity and scientific field.

> "[...] if today we could dare to say that from 90 to 95 percent of all protocols reviewed by the [CEP-Conep] system are directly related to the field of health and maybe 5 percent to other fields, this is not because only 5 percent of the studies involving human beings in Brazil are done in other fields. This is because the fields of law, anthropology, psychology, you know, are not yet adequately aware in order to understand that what they do affects individuals in their personality, the people (I belong to a personalist line), people in their personality [...] as much as the study of the pharmaceutical industry. So the point is that we have to expand by making people aware [...] So there is still a vast area, a huge set of fields that have not yet discovered that a study in the field of education has all ethical aspects of a study in the field of pharmacology, and it can be even more invasive and maybe even more harmful."
> (São Paulo/C4/Bioethicist/05-11)

As one admits that every kind of human activity can be seen from an ethical point of view, all types of study are therefore commensurated. In the bioethical approach, there is no essential difference between a small anthropological study and a multinational randomized placebo-controlled trial sponsored by a pharma company. In the academia, the political particularities of human sciences are thus eventually overlooked. A sociologist, for instance, would have to study a multinational company and its deeds while protecting its confidentiality. Nowadays, any social science study (like my own study) must go through an ethical assessment that copies the biological sciences' procedures.[63] The globalization of bioethical notions, which have been hotly welcomed by most universities, creates a state in which the political dimension of human sciences gets sterilized.

The effects of the communitarian mentality upon the organization of committees have been more timid, because of two main factors. Firstly, as noted before, this approach is much more dependent on sentiments and intuitive notions than its bioethical counterpart, being therefore of difficult translation into oral

[63] While preparing my fieldwork, one Brazilian ethics committee asked me to submit my proposal through the Conep system. The struggle to adjust my study to Conep's rules was so huge and time-consuming that I had to eventually give up and drop that committee from my study.

discourses. The social and political implication of this feature is that people holding communitarian concerns would either engage in voluntary services (an ethics committee, for example) or keep their concerns protected, without voicing them in social spheres. Thus, political and collective programs are not very likely to emerge from communitarian preoccupations.

As an example, one could cite Epstein's study, which identified the emergence of a new attitude toward clinical research in the United States, which Epstein named "inclusion-and-difference paradigm." According to this paradigm, clinical studies must take into account the particular features of women, black people, children, and other marginalized groups. This (*communitarian*) approach has been adopted by scientists, activists, regulators, policymakers (especially in the National Institutes of Health), professional organizations, among other groups, but these actors have not managed to reach high degrees of political organization, a failure that undermines the fast diffusion of their concerns (Epstein, 2007). Thus, communitarian concerns, in spite of being ideologically effective, have failed to be politically effective.

In some instances, people can be led to adopt quite sharp attitudes towards certain policies and technologies. According to Douglas and Wildavski (1982), some groups in the United States have become suspicious of technologies and social changes, which are thought of as threats to society's peace and goodness. This kind of view is also an expression of the communitarian mentality. It tends to be consolidated because as some authors (Slovic, 1999, Finucane et al., 2000) showed, social actors, when assessing technologies, recur not only to objective concepts and calculations but also to emotions and intuitions.

However, some practical policies have managed to stem from communitarian concerns. In South Africa, for instance, the Medicines Control Council, which regulates medicines and clinical trials, has launched a policy called capacity-building. The program tries to encourage pharma companies and CROs to diversify the list of hospitals and physicians they work with, in an attempt to make clinical trials less dominated by a small number of sites and researchers. When submitting research proposals for regulatory approval, companies have to provide justifications if they are not working with non-traditional hospitals and investigators. Even though this policy has not yet produced very important changes, it certainly expresses how (communitarian) concerns with national particularities can shape the state's agenda.

Secondly, the communitarian approach has had little impact over ethics committees because it does not offer a clear and systematic strategy for the practical assessment of research projects (as the bioethical approach does). On the contrary, it tends to instil concerns and criticisms that may sometimes compromise the "productivity" that committees have been looking for. In South Africa, for example, I observed a meeting in which a protocol was discussed whose goal was to assess the effects of a certain therapy upon different racial groups. The study was strongly opposed by one member on the grounds that racial categories should not be used in a country that has been damaged by the apartheid regime. After much discussion, the protocol was eventually approved by all the members, excepting that one member, who hastened to clearly convey her dissatisfaction about the committee's decision. Subsequently, I had the opportunity to interview this member:

> "*And why do you think that race is not a good criterion to be used in research?*
> [...] We have had enormous arguments [in the committee] over race, particularly because people from the developed world (researchers from the developed world) want to come in and look at race as a variable to measure certain population groups in terms of particular behavioural characteristics, because they know that [...] there is still enough coherence among those groups for those characteristics to be measured. And they're often inaccurate, completely inaccurate, because they don't understand what is happening here on the ground."
> (Cape Town/C7/Anthropologist/07-11)

This typically communitarian reply, as well as her emphatic attitude in the referred meeting, shows that the communitarian mentality does not offer much leeway for consensus and concessions.[64] Therefore, this mentality is frequently at odds with the regulatory duties and tight time frames of ethics committees.

However, the communitarian approach did manage to be successful in one point: the participation of lay members in committees. Nowadays, the importance of having lay members is acknowledged even by people who embrace the technical mentality, like the interviewee who voiced the following claim:

[64] In Chapter 6, we shall see that there are important ideological relations between the *communitarian* and *critical mentalities.*

"*Do you think that lay people... people who don't have a medical background can have some problems working in an ethics committee?*

Oh, I think they have a very important contribution, I think, even though they may not feel qualified to delve into the science. But I think they pick up a lot. You know, you look at fifty protocols every year and you start getting a good idea of what's good idea, what's not. But I think that, sometimes, their perspective is... quite refreshing of some of the issues that may not be regarded as such issues by people working in the field [...]."

(Cape Town/C6/Physician/06-11)

To be sure, such claims may be used to make one's discourse sound kind and somehow democratic but, once again, I am less concerned with "truth" (the expression of sincere claims) than with "verisimilitude" (the selection and organization of socially available claims). Anyway, many people, including lay members themselves, also point to dire hurdles to be faced by those who join an ethics committee without having a scientific background.

"I think lay members, after a while, simply can't understand the medical speech [...] I mean, even I, as a social scientist, I don't have the knowledge to always engage. I will listen very carefully because of my academic background and because I've been so long on the committee that I've got a body of expertise that allows me to understand more of the science [...] But I think that for many lay committee members... They must struggle to understand some of what is happening."

(Cape Town/C7/Social scientist/07-11)

"*Do you think that in an ethics committee [as opposed to other areas of the hospital], it is easier for physicians to be friendly?*

I don't know, but they have to deal with other professionals. Of course, that is what I realized in projects that are purely connected to the field of medicine. They are superior in what they talk and discuss, you know. So I can only hear and observe and see how these relations happen in that environment [...]

So with certain topics you feel more comfortable to speak than with others.

> Yes, for certain things... When they begin these too technical conversations, I can only hear, you know. I can only hear because, in fact, it is outside my technical knowledge. So I also take that moment as an opportunity to learn, you know."
> (São Paulo/C2/Nurse/04-11)

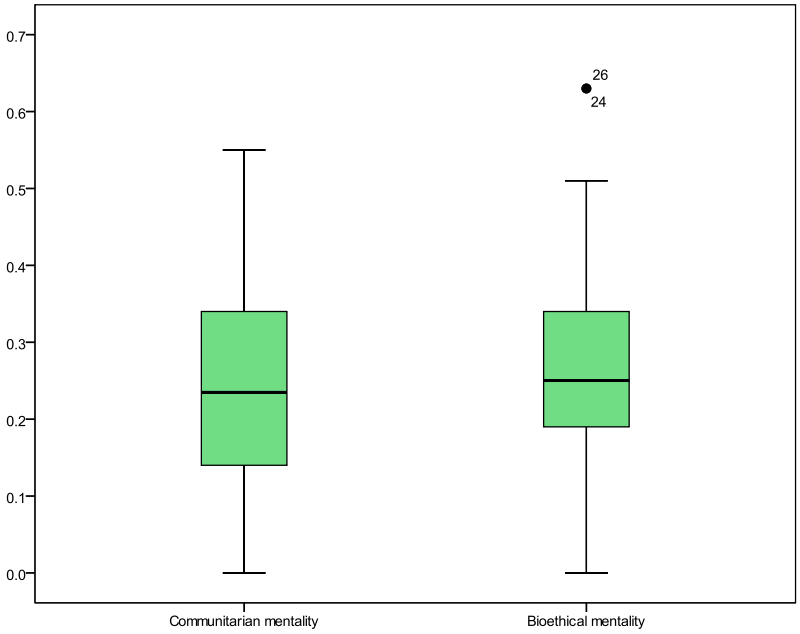
In spite of such difficulties,[65] lay members are most likely to continue to figure in ethics committees, a phenomenon that can be considered as a victory of the communitarian mentality. As explained before, this approach is highly concerned with particularities and, as the communitarian tenets go, "[...] the best way to incorporate particularity into the review process is to invite greater public participation" (Eckenwiler, 2001, p. 38), a claim that echoes the view of other analysts (McNeill, 1993, Robertson, 1979). Thanks to this minor triumph of the communitarian mentality, committees can continue to be a space for encounters between specialists and laypeople or, to use Habermas' (1996, p. 351) words, a space for the "organized contest of opinions between experts and counterexperts."

4.3 Conclusion

The following *discourse boxplots* compare the two *mentalities* focused on in this chapter.

[65] I come back to this point in Chapter 5.

Figure 4.11 – Discourse boxplots: communitarian and bioethical mentalities



Clearly, there is no significant statistical difference between these approaches,[66] which means that they are equally likely to be voiced by committee members. This tendency can certainly be explained by the *complementarity* between these mentalities. Indeed, their claims can be combined in different ways, and this combination never clearly amounts to contradictions. Moreover, it can be said that the *conversation* between these approaches is not only possible but also necessary, because it is often impossible to deal with all the issues involved in clinical research by mobilizing only bioethical or communitarian claims. In this way, these mentalities never cease to provoke and stimulate each other.

It was shown that considering all the mentalities, these two are the ones which tend to influence members' discourse the most strongly.[67] In the case of the bioethical approach, this "success" is due to the following reasons:

[66] We have very similar values when comparing the boxplots. The median is of 0.25 and 0.23, respectively; the standard deviation is of 0.14 and 0.13.
[67] See Figure 4.2, page 110.

- There are socially diffused concerns with past scandals verified in clinical research
- This approach makes it possible to apply a mythical thought that appease dilemmas and appears to solve ethical problems
- The organization of committees is highly informed by international (bioethical) guidelines
- Bioethical notions permeate committees in several ways (talks by specialists, courses to committee members, principles stated in regulations, among others)
- The bioethical mentality has decisive practical and procedural consequences, for it marshals general principles, commensurates research projects and opens up much leeway for a standardized processing of research proposals
- It also introduces a seemingly objective calculation between risks and benefits, a notion that can be especially instructive for new committee members

As for the *communitarian mentality,* its "popularity" stems from different factors:

- There are socially diffused concerns with the preservation of particularities
- Social and international inequalities have proved long-lasting, fostering the permanence of compassion as a social driving force
- Groups considered as socially vulnerable are increasingly recruited in clinical studies
- Many people recognize that even in highly regulated and scientifically designed studies, uncertainties cannot be circumvented
- Committee members are aware that they have much to learn not only through written documents but also through relations within the committee

The bioethical approach has been more efficient at forming a theory to underpin the committee members' tasks. Probably, this is why many social science studies have focused on the impacts of bioethics, whereas communitarian concerns

have been less intensely addressed as a decisive factor of moral assessments. Thanks to its theoretical performance, the *bioethical mentality* allows a smooth passage towards the *technical mentality.* There is also a pathway leading from the *communitarian* to the *analytical mentality*, but this passage is less straightforward, insofar as the communitarian approach is easily influenced by several types of concerns, including *instrumental* ones. This is one of the issues addressed in the following chapter, which focuses on the *technical* and *analytical mentalities.*

Chapter 5 – Global trials and foreground knowledge: the technical and analytical mentalities

In this chapter, we focus on two other approaches to clinical research. As they are organized with some scientific concepts, it is important to begin with a review about the connections between ideology and systematic thought. After this review, we start focusing on the technical and analytical approaches. Initially, we address the only characteristic shared by them: their concern with methodologies advanced in clinical studies. Subsequently, we explore their disagreements and ideological conflicts, focusing on issues like regulations, globalization, views about ethics committees, among others.

5.1 IDEOLOGY AND SYSTEMATIC THOUGHT

In this chapter, we arrive at a level in which ideology is fostered by scientific explanations. Thus, it is important not to succumb to the idea that science constitutes a morally and ideologically neutral universe. This idea was one of the pillars of the positivist project. Indeed, one of the main ambitions of the positivist philosophical tradition is the construction of a scientific and philosophical explanation based on so-called facts whose occurrence and assessment would not depend on individual and contextual factors (Carnap, 1966). Although this ambition can be seen as non-realistic, it has inspired many scientists all over the world.

Sociology has devoted great efforts to the comprehension of ideological projects lurking behind apparently neutral scientific explanations. A well-known contribution was given by Marx (1867/1990), who proposed that scientific models (and Marx focused on scientific economy) belongs to a political project of class domination. The equally classic Weber's analysis follows a different pathway. For him, science delivers a sort of ideological underpinning upon which a blend of practical, bureaucratic and moral rationales outgrows its strength, making it possible to undertake several sorts of "actions directed to ends." Science furnishes the modern

world with basic conceptual and technical resources, which remain ignored by the majority of social agents (Weber, 1930/2001).

Drawing on these classic interpretations, Arendt (1951/2004) further explored the mystifying capacities of science, showing that in totalitarian political regimens, ideological control was based on the circulation of superficial, and sometimes distorted, scientific notions through the media. Marcuse (1964/1991) also undertook an important study on the "ideology of advanced industrial society," a theoretical effort to which Habermas (1973) himself adhered to at the beginning of his career. More recently, authors have pointed to the role played by scientific concepts in the global diffusion of feelings of risk (Beck, 1986/2005), the scientific contributions for a global planning that is largely controlled by multinational companies (Santos, 2000), the interference of science experts in regulatory matters (Jasanoff, 1990), or the upheavals promoted by the sciences of communication, making it possible to constitute a "network-society" (Castells, 2004).

What has to be stressed is that, in the classic analyses briefly mentioned, one identifies the important idea that science implies many types of blends between conceptual and political projects. In this way, the formulation (or critique) of scientific concepts has consequences not only for scientists but for the whole society. At the same time, the aforementioned studies bring about the idea that complex scientific theories can be translated into simplified forms, therefore being able to influence vast ranges of social actors.

The theory of communicative action (Habermas, 1981/1987, Habermas, 1996) grasped this last phenomenon with an unprecedented success, stressing that technically efficient actions, as well as sophisticated theoretical structures, would still be socially and ideologically sterile without being at some point integrated into the communicative flow that crosses over society. In other words, the technical and ideological supremacy of some actors can only be secured and maintained if this supremacy is somehow recognized and reinforced by all types of social actors. Therefore, political hegemony cannot really exist within closed social subgroups; it depends on tasks of social integration.

> "For such tasks, an ordinary language is available, circulating throughout society and lying beneath the threshold of the special codes. In the peripheral

networks of the political public sphere and in the parliamentary complex, this ordinary language is, in any case, already in demand for dealing with macrosocial problems" (Habermas, 1996, p. 352).

In Chapter 3, in which *background knowledge* was focused on, it was claimed that pragmatic notions are strong and effective because of their accessibleness, that is, the fact that they can be rapidly understood and communicated by every social actor. In the present chapter, we deal with two mentalities whose connections to *background knowledge* are indirect and sometimes almost impossible. However, even the *technical* and *analytical mentalities* (which are addressed in this chapter) need to be translated into the ordinary, "natural language" (Habermas, 1996, p. 360) that is generally mastered in society. This is the first point to be made in our description of these two new approaches: both the *technical* and *analytical mentalities* draw on many sorts of medical, statistical, sociological, clinical, biological concepts; yet we are not dealing with *codes*, in the sense that these mentalities would constitute closed universes to which only experts would have access. On the contrary, they can only be effective and solid because they are integrative, in the sense that all categories of committee members, from lay people to physicians, can somehow access and understand their contents.

In the following section, we analyze a trait that is shared by these two approaches.

5.2 ASSESSING METHODS

By reading the descriptions and quotes presented in the previous chapter, one might be intrigued by the following circumstance: in the *bioethical* and *communitarian mentalities*, people voice moral discourses about clinical trials without delving into the actual scientific aspects of clinical studies. Indeed, concerns with vulnerability, particularity, ethical principles, inequalities and so on, can be advanced without the consideration of methodologies, samples, tests, study arms, among other procedural details. In the *technical* and *analytical mentalities,* these methodological concerns are finally voiced. By the way, this methodological attention was the main feature allowing

me to “confirm” the existence of the technical approach (hypothesized before the fieldwork) as well as “discover” the analytical approach (unravelled by means of my interviews). I am referring to claims such as the following ones.

> “*When you’re reviewing a protocol, what is your main concern?*
> Obviously, I ask: Is it scientifically... Does it make sense, scientifically? And it has to be justified. I mean, is there no other method of finding out? So you look at the design. Is it right? Is it okay? And then, eventually, you look at the ethics. But you have to look at the scientific soundness [...].”
> (Pretoria/C8/Bioscientist/07-11)

> “*How would you define a good protocol, a protocol that is properly presented?*
> It depends on the phase, it depends on the structure that you... on the moment when that protocol is presented. Obviously, any protocol depends, basically, on an adequate justification of its goals and also on proper methodology. But it all depends on the phase in which you run that protocol in, whether it is phase I or phase III or multicentric, industrial... Every protocol has its characteristics.”
> (São Paulo/C3/Physician/04-11)

Here, we leave the contextual and philosophical approach to clinical studies (as showed in the previous chapter) and move towards a more substantial and direct view. This methodological concern is the basic feature of both the *technical* and *analytical mentalities.* Actually, this is the only point on which they agree. In contrast to the relationship between the bioethical and communitarian mentalities, the technical and analytical approaches do not engage in frequent *conversations*. As depicted in Figure 3.1 on page 71, at this level there are much more frequent “vertical” conversations (either technical-bioethical or analytical-communitarian) than “horizontal” conversations (technical-analytical).

The aforementioned attention to methodologies, for instance, can be combined with both bioethical and communitarian claims. In the following quotes, I am breaking some interviewees’ replies in different parts:

Question
Technical/Analytical
Bioethical/Communitarian
Technical/Analytical
Bioethical
Technical/Analytical
Bioethical

"*When you're reviewing a protocol, what is your main concern?*

Main concern to look at is, obviously, the appropriateness methodol... Let's say, back to start, it is the study objective, the questions asked (aims and objectives). Is that appropriate? Is the methodology appropriate? I tend not to go too much into the basic science behind it because I think this is not the responsibility of the ethics committee, but around that, everything largely related to the subjects, to the patients, to the volunteers... patient-related issues.

Inclusion criteria of the patients,

risk-benefit for the patients,

and an issue is, with respect to experimental drugs, to make sure that the patients have what is called equipoise (you know that?), that... that the two options that they have are more or less, at that point in time, sort of equivalent [...]

Declaration of Helsinki and all these discussion points. And it is often the informed consent form that is difficult [...] Ethics committees, if they have a comment on a protocol, that is the informed consent form."

(Cape Town/C6/Bioscientist/08-11)

Question
Bioethical
Technical/Analytical
Bioethical
Communitarian

"*Is there any section of the protocol that you consider as more important?*

For me, as a layperson [laughter], it would probably be the informed consent form but then, also [...],

if a clinical trial is not scientifically sound, then how can we give ethical clearance to that kind of trial? [...] my view is, if the science of a clinical trial is wrong, then you cannot give ethical clearance to it. Like, for instance, inclusion and exclusion criteria. If you include in there people that shouldn't be there... somebody has to evaluate that [...] So what I'm saying is that the methodology needs to be correct and all the other scientific aspects of the study need to be correct as well.

So for me the importance is, firstly, your informed consent form because, of course, there are consent forms that are not really *informed*, because it may be just a little bit of information [...]

And remember I said earlier: our people are not really that well-versed, the people that are usually taken up in trials at this hospital and in this area."

(Cape Town/C6/Nurse/08-11)

Having identified this methodological concern, which is a point on which the technical and analytical mentalities go hand in hand, we begin to address, in the following section, the marked ideological differences between these two approaches.

5.3 THE TECHNICAL AND ANALYTICAL MENTALITIES

Concerns with methodologies in clinical studies constitute the only aspect that could be framed as "politically neutral" in the technical and analytical mentalities. From now on, political issues become paramount. In a sense, one can say that the technical and analytical mentalities also share a philosophical characteristic: although they initially focus on research projects' details carefully, in subsequent moments they go beyond these methodological issues in order to engage in a debate about the ways in which clinical trials are assessed both in committees and society. Two major consequences stem from this circumstance.

On the one hand, discourses assume a less pronounced moral vein (in terms of "this is not good for us to be doing") to acquire more political contents (in terms of "this is the best way to discuss the issue of trials in committees and society"). On the other hand, my text itself is affected by political considerations and it gets more and more difficult to describe mentalities without suggesting my personal view about their worth. The description of mentalities cannot be done from an abstract point from which one can look at *mental life* without being influenced by any mentality. As it seems to me, my interpretation is voiced from an *analytical* point of view, a claim that is valid not only for this chapter but for my whole thesis. This consideration is in tune with the theory of communicative action, which invites the analyst to join the communicative processes of society, rather than subscribing to "*theoretical* explanations of an interpreter who adopts an *objectivating* standpoint" (Habermas, 2008, p. 60). However, adopting an approach (that is, favouring claims derived from a particular mentality) does not compromise sociological analysis as long as this preference does not lead us to overlook other mentalities.

Having advanced this clarification, we move on to discussing an initial discordance between the technical and analytical approaches.

5.3.1 Clinical trials and scientific accuracy

There are very different reasons why the technical and analytical mentalities draw attention to methodological issues. In the technical approach, this precaution is important insofar as committee members would be supposed to measure, as it were, the distance between the established scientific standards and the standards adopted in a particular research project. Thus, the basic assumption is the very existence of objective, identifiable, recognized scientific standards and yardsticks. This assumption is identified in claims such as the one advanced by Abraham (1993, p. 390):

> "[…] given certain socially derived and commonly agreed standards of communication and reason, objective assessments of knowledge claims can be made by reference to those standards. Although scientists sometimes disagree wildly, such assessments are sometimes possible because frequently scientists do agree on some standards."

Once this idea has been assumed, it becomes easier to accept that scientific standards must be not only acknowledged but also improved. From this standpoint, clinical research would be an endless enterprise through which scientific standards are tested and scientific knowledge advanced. Hence, the idea that in clinical trials, researchers are collecting data and gathering evidence in order to improve human knowledge of health and illness.

> "*In your opinion, what is the main goal of clinical research?*
> [...] It is to get observations that we can extrapolate into the future to... to get information that would give us the best guess of which direction we should go. Advancement of knowledge. Generalization of knowledge."
> (Cape Town/C6/Physician/08-11)

> "*In your opinion, what is the main goal of clinical research?*
> Advancement.
> *Sorry?*
> Advancement.

Advancement. What does advance [laughter]?

I think that, you know, the application of methods, the application of medicines... Advancement, actually, in terms of technologies. Because I see new things that men try to standardize... Advancement and standardization [...] You have a medicine for a certain thing and now you're seeing that it can be used for another thing; there has been an off-label use and you're doing a study to prove that it can be used for that other thing, and that there can be another indication for it, otherwise you can't officialise that indication [...]."

(São Paulo/C3/Bioscientist/05-11)

Thus human progress can be looked for because there are technologies and standards in need of constant improvement. The idea of scientific standards has a twofold implication. On the one hand, research can be done in accordance with these guidelines. On the other hand, guidelines can be violated and therefore turned into references with which one could measure the size of scientific errors. Consequently, the technical mentality leads to the recognition of good and bad studies. This is what one of my interviewees claimed about clinical research:

"*If it is well done, it will advance knowledge.*

It will advance knowledge [...] You're talking almost like blue-sky-research. Clinical research is not blue-sky-research but I also think that there is a place for blue-sky-research, in other words, knowledge for the sake of knowledge...

But most of times, it is not blue-sky-research, then.

Not all clinical research is blue-sky-research but we do sometimes encounter research which I would say is blue-sky-research, not necessarily intended for direct application but I mean, you know, you have to start somewhere, you build on little blocks of information and eventually it might lead to something else [...]."

(Cape Town/C6/Physician/08-11)

On this point, the technical mentality shows its brotherhood to the bioethical mentality. In the previous chapter, it was claimed that the bioethical approach admits the presence of goods and bads in clinical research, striving to calculate the risk-benefit ratio. Equally, the technical approach assumes that research can be either good

("blue-sky-research") or bad. Studies would not be worth conducting whenever they are not in tune with what Abraham (2007, p. 732) described as "valid/coherent knowledge claims." By means of a simple ideological operation, the ideas of knowledge and research are given a moral content, thus being presented as social targets.

> "*So it is possible to say that statistics is also a way to protect people in a protocol.*
> I think it is definitely. It is essential [...] I mean, if you put people into a trial which cannot detect what constitutes a clinically relevant change, I think that is very unfair [...] It is unethical if we subject people to an experiment which cannot lead to the required or to the anticipated result."
> (Pretoria/C8/Bioscientist/07-11)

> "[...] I think research is good. So I won't try to interfere or damage it because it is research. I think research is good *a priori,* because of the examples I gave you: it obliges physicians to study, it obliges to be committed to science, it obliges to be familiar with very innovative things [...]."
> (São Paulo/C2/Physician/04-11)

Therefore, research comes to be seen as a promoter of not only the advancement of knowledge but also the moral soundness of society. This ideological operation can be taken to even higher degrees and then research becomes a prerequisite for human progress. Jonas (1969, p. 230) described this ideological stance as follows:

> "[...] science is a necessary instrument of progress; research is a necessary instrument of science; and in medical science experimentation on human subjects is a necessary instrument of research: Therefore, human experimentation has come to be a societal interest."

Some of my interviewees' claims echoed this logic.

"Are you *not concerned with the fact that there are studies sponsored by companies?*
No! No. Well, whenever you have research, you have interest behind, either the academic interest or this academic interest associated with a commercial or industrial interest [...] Financial interests. We live in capitalism. And this is not always bad. This can bring about benefits for society, especially when we talk about new drugs [...] Everything that is developed in the world is developed through research, be it research on human beings, be it research on cement, be it research on atoms, be it research on... whatever [...] The development of society is realized through research, through the observation of phenomena [...]."
(São Paulo/C2/Nurse/04-11)

"*Well, you have talked about that quickly but I would like to ask: in your opinion, what is the main goal of clinical research?*
I think it is, first, to assess and develop new drugs (in terms of medicines), new procedures (in terms of surgeries, nutrition and also physiotherapy) [...] In a sense, everything must go through research [...] Piaget said that all knowledge is based on organization and adaptation. So all the knowledge that comes from clinical research is aimed to organize the new procedure and adapt your behaviour to this procedure [...], otherwise medicine would be paralyzed, you know, you wouldn't have had this incredible progress you've had over the last years. Look, thirty years ago, all you had was the X-ray. Nowadays, you have a device that tells what is going on with you almost at the level of your cells. This is an incredible progress. Thirty years ago, people died of prostate cancer, people with breast cancer, when they got to the hospital, were already at a degree... Nowadays, we lose very few people because of that. The evolution is indisputable. I'm not talking about Brazil, I'm talking about the world, about medicine. It is indisputable, Edison [...]."
(São Paulo/C2/Physician/04-11)

Things would not be considered as indisputable by people holding analytical concerns. Indeed, the analytical approach is also most interested in research methods but its attitude is rather cautious, if not suspicious. Analysts have scrutinized the scientific, statistical and clinical procedures generally used in clinical trials. According to these analyses, clinical researchers can sometimes prevent research failures from

emerging and force the evidence they are looking for to appear. These are some of the strategies that have been identified:

- By making inclusion criteria very stringent, one would be able to select a study population that is likely to show a good performance for the candidate drug (Petryna, 2009)
- When the candidate drug is compared to a competitor's drug, this latter can be used in doses that do not reflect its normal use, enhancing the positive performance of the candidate medicine (Petryna, 2009, Shah, 2006, Busfield, 2006)
- In one-to-one comparisons, the performance of the proposed medicine can be improved if research subjects were asked to take parallel medicines in addition to the candidate compound (Petryna, 2009)
- In trials for drugs to be used in elderly people, only young people could be recruited. As young people tend to show fewer side effects, the appearance of safety would then be enhanced (Shah, 2006)
- Prior to the actual conduct of a trial, pilot studies can be conducted in order to identify and exclude research subjects that prove to be more likely to respond to placebos (Lakoff, 2007)

"Needless to say, without such protocol tinkering, differences between newer and older drugs treating similar conditions would in many cases be narrowed substantially" (Petryna, 2009, p. 83-84). Here, there is a concern with pharma companies' and CROs' operations, as one assumes that they "[...] make the facts and select the data that are reviewed by the approval agencies" (Busfield, 2006, p. 305). Focusing on different types of clinical studies, some analysts concluded that, compared to academic research, trials sponsored by companies are more likely to show positive results (Kjaergard and Als-Nielsen, 2002) and that companies fail to publish data when study results counter their expectations (Turner et al., 2008, Chan and Altman, 2003, Chan and Altman, 2005).

By paying attention to such examples, one comes to refuse the idea of potentially sound studies conducted in accordance with the established scientific

standards. Considering that clinical research has been dominated by multinational companies (an assumption that is inherited from the *pragmatic mentality*), holders of the analytical approach point out a different "standard": the savviness of companies and researchers that are always willing to "'engineer up' the success of trials," to use Petryna's (2009, p. 187) expression. These same concerns were voiced by a small number of my interviewees.

> "*Do you consider the meeting as the most important moment in the committee's work?*
> Er... no. The most important moment is the analysis of the project. It must be well-analyzed, you need time for that, it takes time. You need to research. Sometimes we have to check whether one reference is accurate or not. From time to time the references are not really adequate; that has happened since some time."
> (Porto Alegre/C5/Physician/05-11)

> "*Is the review something that takes you much time to do?*
> It depends on the project [...] The test of a new medicine, you know, how do I do this review? It gives me much work. I go on Medline, I look at the summary of the last publications, I see, among the last publications in Medline on that drug, those who are not sponsored by pharma companies (because we have the information that projects sponsored by the industry tend to show much superior results than studies done in universities without funding from companies, you know), another resource I use, when I get too concerned [...], is the British National Formulary, BNF[68] [...], and based on that, I make solicitations. For instance, BNF, the last time I went onto it, I found, for a drug under study, a counter-indication, on BNF, that had not been pointed out in the project. So I asked them to put that specific condition into the exclusion criteria, according to what BNF said."
> (São Paulo/C3/Social scientist/05-11)

From this point of view, committee members would be responsible for a sort of scientific investigation, in order to unravel methodological inaccuracies.

Obviously, the technical and analytical mentalities look at multinational companies and globalization with different eyes. In the analytical approach, global

[68] Medline and BNF are two online databases with biomedical information and literature.

companies would be actors endowed with a huge capacity to tinker with protocols. In the technical approach, companies are seen as competent and resourceful promoters of clinical studies. As one of my interviewees put it, "[...] the industry is very developed and they prepare good protocols [...] I won't give their names but it is just a pleasure reading those people's protocols [...]." Bellow, I compare two claims voiced by two different interviewees, as well the *discourse graphics* derived from their interviews.

Analytical	Technical
"*Do you think it is possible to say that in clinical research, people are testing drugs but they are also testing scientific methods?* [Pause.] [...] I don't think so. I'll tell you why. I think... Again... Let's take two situations. I think, if you take pure academic research, then they are. If you take drug companies, you're not; you are there to show that a drug is better [...] I speak in the correction [...] Er... if a company organizes a drug test, it is three times more likely to be positive for their drug than if an independent researcher organizes that research. So I think the message is there. I think it is three, it might be four, but I think it is three times."	"*Do you remember a moment of big disagreement [in a meeting]?* Yes, I have disagreed, strongly, with somebody about a clinical trial where I had the impression that because it is a big drug company, there is an assumption that they're doing something wrong and that it isn't carefully thought about what is being done. And, also, I know that when a big drug company puts together a very large study costing millions if not billions these days (I mean, we've got a trial that is recruiting 22,000 people; it is a very controversial trial)... but I also know that when they put that protocol together, they've got all the experts around the table, and it wasn't an evil person in a drug company deciding how to do the great harm in order to do a big profit [...]"

Figure 5.1 – Discourse graphic n. 29

(Cape Town/C6/Physician/08-11)

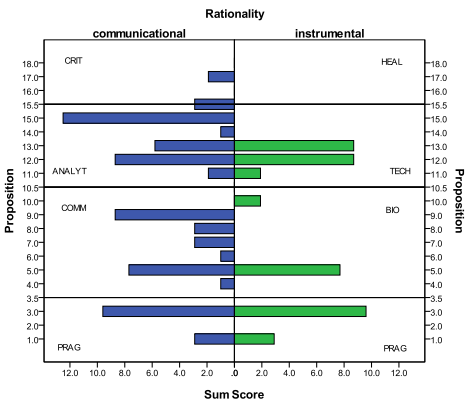
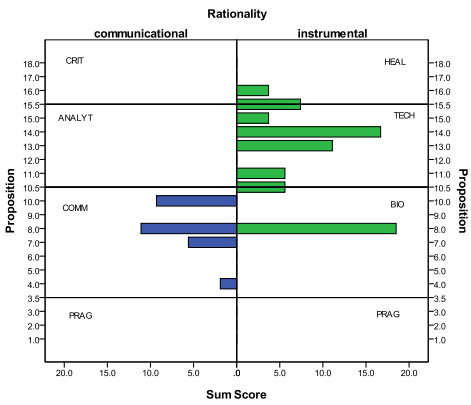


Figure 5.2 – Discourse graphic n. 20

(Cape Town/C6/Physician/06-11)



In these examples, we have two people with the same background (medicine) and sitting in the same committee, but embracing two different mentalities. These *discourse graphics* show how the technical approach tends to draw on bioethical claims (one simple claim in the example above), while the analytical approach is underpinned by communitarian and pragmatic concerns.

The example shown above lets us observe another crucial argument in the technical approach: trials sponsored by the industry are said to be more accurate than academic studies because companies hold more financial resources to set up appropriate research structures. In a report prepared for the Association of Clinical Research Organizations, it is claimed: "Although problems with trials sponsored by multinational companies are likely to receive more press attention, ethical and quality violations often occur in trials initiated by local investigators" (Voi Consulting, 2009, p. 15). In the technical mentality, another claim tends to be repeated: "The creation of a new drug is risky and expensive" (Wood, 2006, p. 618), an idea that suggests the scientific accuracy of wealthy companies.

> "*So it is possible to say that the business goals of the industry enhances or improves the scientific goals of trials.*
> It goes hand in hand. The basis is the business goal and that improves the science in the way that, for example, the sample sizes must be appropriate. If you don't get the appropriate sample sizes, you run the clinical trial for ten years and at the end of the long way doing clinical trials, nothing is significant because the sample size is not appropriate. And that is something industry wouldn't do [...] So their design of clinical trials is very good [...]."
> (Cape Town/C6/Bioscientist/08-11)

> "*So the main difference between the academic and the industrial research would be the scientific expertise.*
> I think that is the one part and the other is the quality in terms of conducting the trial. In an academic trial, you don't have the kind of resources and the support staff that you do for an industry-conducted trial where CROs come in and do a professional job with administrator support etcetera. So there is a big difference from that point of

view. The regulatory oversight is different. The science of the trials is very different [...]."

(Cape Town/C6/Physician/06-11)

From this technical point of view, the globalization of trials appears as scientifically desirable. In the statistical explanation given by Marschner (2010), for example, three reasons are presented that would justify the conduct of global studies: the advantages of multicentre studies can be enjoyed at the global scale; results are more generalizable; and there is less need for replication, for many ethnicities are involved in the study. Thus the technical mentality frames the globalization of trials as a scientific imperative. In its turn, the analytical approach considers globalization as a phenomenon that enhances the power of multinational companies, expanding the leeway for scientific tricks in clinical research.

To summarize, the technical mentality operates with the idea of scientific standards, subsequently suggesting that big companies have more resources in order to comply with them. On the other hand, the analytical mentality, directly influenced by pragmatic and communitarian concerns, stresses the tricks that can be done while designing and analyzing clinical studies, a phenomenon that requires a more cautious attitude towards companies. In the following section, we focus on these two approaches' sources.

5.3.2 Philosophical and historical sources

The emergence of the technical mentality has to do with a very long historical development. It is part of a process that Weber (1968) captured with the idea of "rationalization." Into the framework of this slow development, one can certainly include social products such as bureaucracy, management, science, accounts, among other creations whose effect has been the reduction of the leeway for "subjectivity" in key domains of social life. As Porter (1992, p. 646) claimed, "[…] science enshrines objectivity, meaning (here) not truth to nature, but impersonality, standardization – reducing subjectivity to a minimum."

We are dealing with a powerful mindset that derives abstract and general categories from concrete examples. Applied to the domain of medicine, this mindset has led to a conception of the human body in which organic and biological differences are seen in the light of general concepts. “One quality attributed to the natural sciences is the independence of their established facts from local contexts: a given chemical element or a chromosome is the same ‘thing’ whether studied in San Francisco or São Paulo” (Lakoff, 2005, p. 3). According to Lakoff (2005, 2007), the medical thought came to frame diseases as something existing outside of human bodies, allowing for more and more ambitious generalizations, until the point in which recent techniques, such as genomics, can aspire to eventually become universally valid.

Thus, the idea of general and objective knowledge (which appeared in some of the technical claims previously quoted) is also a historical product. Thanks to a long development through which concepts and procedures were slowly harnessed, one could eventually generate the idea of conclusions “springing directly from the facts,” an image that testify to the “cultural authority of science,” to use Gillespie, Eva and Johnston’s (1979, p. 294) words. However, in order to fully grasp the technical mentality’s features, it is important to consider how scientific conclusions are generally obtained.

According to Arendt (1958/1998), modern society, by developing its productive forces to unprecedented levels, ended up putting the idea of production at the centre of its philosophical framework. Consequently, no human activity is really favoured without being somehow related to the fabricating process through which men change their material environment and add new useful things to the world. Science could not escape from these processes, and the main implication was the central role attributed to experiments. In fact, experiments are procedures through which scientists establish a material arrangement (the fabricating side of science) and glean scientific knowledge (the cognitive side of science). “The use of the experiment for the purpose of knowledge was already the consequence of the conviction that one can know only what he has made himself [...] The experiment repeats the natural process as though man himself were about to make nature’s objects […]” (Arendt, 1958/1998, p. 295).

Clinical studies can be seen as experiments in which researchers try to produce scenarios that imitate the processes of nature. In this way, they reinforce “the modern

blending of making and knowing" (Arendt, 1958/1998, p. 296). The technical mentality could not exist without being underpinned by this active stance of science, nor would it be effective without the medical view of bodies, diseases and drugs.

It is important to stress that all these ideological constructs belong to very broad processes encompassing many social domains. The Industrial Revolution represented a watershed in this history.

> "The avalanche of numbers, the erosion of determinism, and the invention of normalcy are embedded in the grander topics of the Industrial Revolution. The acquisition of numbers by the populace, and the professional lust for precision in measurement, were driven by familiar themes of manufacture, mining, trade, health, railways, war, empire. Similarly the idea of a norm became codified in these domains" (Hacking, 1990, p. 5).

From the viewpoint of the theory of communicative action, all these developments can be said to have reinforced the instrumental mentality, making social groups more controllable and social actions directed to ends more precise. Thus, the technical aspect of society has grown bigger and bigger, in the double sense that groups can be technically shaped and controlled like *instruments*, on the one hand, and that the impacts of social actions can be anticipated more accurately, on the other. This is true not only for practical actions but also for *discourses,* which can be voiced in order to provoke predictable reactions. I am referring here to the *instrumental* use of language, a possibility which was pointed out by Habermas (1981/1987) himself. It is because of this *instrumental,* technical use of language, which draws on broad social, philosophical and historical processes, that I speak of *technical* (rather than medical or scientific) *mentality.*

In this very brief historical overview, one should not forget the pivotal role played by the statistical thought, which is decisive in clinical trials as well. On this point, the first ideological upheaval was provoked, at the end of the nineteenth century, by the idea of sampling, according to which some individuals, if carefully selected, can be considered to represent the whole population. "This was unthinkable during most of the nineteenth century. The very thought of being representative has had to come into being. This has required techniques of thinking together with

technologies of data collection. An entire style of scientific reasoning has had to evolve" (Hacking, 1990, p. 6-7). In many domains, including those which have to deal with individual and apparently untameable variations (like medicine), statistics has proved invaluable precisely because it can turn variety into regularity, rebel inconsistencies into obedient measures. Thanks to blends of mathematical and statistical tools, the rationalization of society advanced many steps forward, for according to Arendt's (1958/1998) interpretation, it was now possible to penetrate any series of objects and events, which could be rapidly submitted to numerical orders.

Statistics never cease to show its ability to cope with large numbers, a characteristic that can only be highly treasured in a mass society. "There is a seeming paradox: the more the indeterminism, the more the control" (Hacking, 1990, p. 2). The next step was the admission that the regularities and "normalities" presupposed by statistics, instead of deriving from human speculations, must be an inherent characteristic of the world and society. From a methodological tool used to undertake some (more or less conclusive) tests, statistics have turned into a "synthetic *a priori* truth" (Hacking, 1990, p. 104), especially for those who display the disposition to "trust in numbers" (Porter, 1995).

The *technical mentality*, having achieved this stage in which quantification is not only possible but also necessary, is rapidly endowed with an important political feature. With this numeric clothing, it can be globalized more easily, for as Porter (1992, p. 644) argued: "Quantification is a form of rhetoric that is especially effective for diffusing research findings to other laboratories, languages, countries and continents." Therefore, two phenomena made the globalization of the technical approach likely to occur. On the one hand, the simple fact that (by means of *pragmatic* notions) people of different countries become *concerned* with similar issues pertaining to clinical trials. On the other hand, the globalization of trials necessarily entails the use of mathematical and statistical concepts with which clinical protocols are designed. In this way, committee members have to deal, at some point, with the historically and philosophically powerful notions of the technical mentality, according to which research proposals should be analyzed in the light of scientific standards, statistical methods and objective yardsticks. Hence, some claims such as the one voiced by one of my interviewees.

"*Do you think there are fundamental differences between an academic study and a trial sponsored by the industry?*

Ah. Well, that question can be answered in very different ways. So... Scientifically, there shouldn't be, right? Scientifically, they should have the same standards, the same guidelines, the same... the same... the same sort of mode of producing acceptable knowledge. So over five hundred years of science, we have come to certain standards of valid and true and objective knowledge, and pharmaceutical research should follow those equally as academic research should do [...]."

(Cape Town/C7/Bioethicist/08-11)

Compared to this ideological history of the technical approach, the analytical mentality can be said to be in its childhood. Actually, one can say that it begun to be formulated in the 1980s, as a consequence of social and scientific developments of clinical studies. The first observation making it possible to formulate analytical views of trials was the flexibility displayed by some drugs, whose final application had little or nothing to do with their initial intended use. As Abraham (2007, p. 733) explained:

> "[…] scientists have tried [...] to construct numerous drugs for particular therapeutic and market categories only to discover during clinical trials that the drug-human biochemical interaction produced a completely unexpected outcome resulting in the drugs being marketed for entirely different therapeutic purposes from those initially constructed (e.g. Viagra)."

From these observations, two crucial ideas have been gleaned. Firstly, the hypothesized accuracy of science has been contested by some analysts who have observed researchers struggling so as to confirm their "guesses" via clinical trials. Secondly, analysts came to unravel the flexible nature of trials, concluding that in the same ways in which one trial can be rethought and redesigned in order to produce evidence in a new way, it can also be rethought in order to be analyzed and shown in a different and sceptical light.

One important event underpinning the emergence of the analytical mentality was the revelation of inaccuracies (frauds?) undertaken in some clinical studies. For instance, McGoey and Jackson (2009) analyzed the case of Seroxat, a GlaxoSmithKline's drug that remained in the market even after the company had discovered that it was not only ineffective for its targeted disease (childhood depression) but also increased suicidal tendencies in children. Another example is Vioxx, a Merck's anti-inflammatory that remained in the market until 2004. It was lately discovered that, in 2001, the company had had enough evidence about the cardiovascular risks entailed by the product (Juni et al., 2004, Psaty and Kronmal, 2008, Topol, 2004). In Chapter 4, it was claimed that the bioethical approach is fostered by the remembrance of past scandals in clinical research. Now we see that the analytical approach is concerned with some historical examples as well. Nevertheless, one difference needs to be pointed out here. Whereas the bioethical mentality focuses on relatively old examples (such as the Nazi studies or the Tuskegee scandal), the analytical mentality evokes more recent stories, suggesting that they are somehow here, lurking and waiting for the opportunity to happen anew. In addition, the analytical approach does not focus on moral issues (such as exploitation, deception and consent to research) but delves into scientific and methodological failures of studies.

In spite of these procedural concerns, the analytical approach does not depend on codes and specialized languages. On the contrary, its emergence was mainly due to actions of people who did not have a scientific background. On this point, Epstein's (1996) book is crucial to understand the formulation of this approach. He studied the conduct of the first Aids trials in the United States, during the 1980s, a period when scientists had a very poor comprehension about this disease's mechanisms. As no previous knowledge on HIV was available, studies were based on purely hypothetical assumptions. As a consequence, researchers realized that it would be interesting to work in cooperation with patients and Aids activists, who held a personal knowledge that could bring about important inputs to studies. "Some researchers therefore came to welcome, or at least acknowledge benefits of, activists' participation in the design of clinical trials" (Epstein, 1996, p. 336).

The events described by Epstein constituted a decisive point of departure for the analytical mentality. Stunned by the march of a mysterious and murderous

disease, society put the power of science under scrutiny. Suddenly, all scientific knowledge that had been gathered during centuries proved futile and some scientists decided to draw on some lay knowledge provided by those who directly experienced the disease. The analytical mentality is fostered by this idea that in some situations, lay "invasions" of medicine may lead to desirable results. The first Aids trials represented a historical opportunity to unravel something that, mostly, comes to pass in very subtle ways: lay people are not mere receptors of medical knowledge; rather, they assess this knowledge on the basis of personal feelings and experiences. For instance, patients, in order to take decisions about their diseases, consider what is said by physicians but also consult their own feelings and the opinions of friends and relatives, engaging in dialogical relations that are decisively influenced by contexts (Ehrich, 2003, Rapley, 2008).

Thus, the analytical approach is also nourished by the laypeople's confidence at delivering some inputs to medicine. In clinical trials, this attitude is made possible because of two circumstances. On the one hand, as Epstein (1996) noted, researchers do not always agree as to whether study results must be interpreted in one direction or another. In fact, drawing on exactly the same data, investigators may advance completely discordant conclusions (Abraham, 1993, Richards, 1988). In these occasions, the feedback from patients may acquire a special worth. On the other hand, there are some clinical studies (in areas such as cancer or other rare diseases) in which the conversation between experts and subjects is paramount to assess the actual effects of candidate drugs. Thus, in spite of the often obscure language spoken within clinical studies, there is still some leeway for lay interventions. "This more immediate role of patients in clinical research, combined with the relatively greater accessibility of research methods to lay comprehension, explains the enhanced capacity of laypeople to intervene in debates about trial design and interpretation" (Epstein, 1996, p. 337).

In ethics committees, non-medical "invasions" of medicine are also likely to occur, as some proposals pertaining to clinical trials come to be analyzed by nurses, lawyers, social workers or lay members. Even though physicians continue to be favoured in the review of medical studies,[69] some members who lack a medical

[69] I come back to this point in the next chapter.

background do manage to obtain a certain amount of expertise, which enables them to gauge some substantial scientific aspects of protocols.

The history of the technical mentality is completely intertwined with the history of clinical trials; one can certainly say that trials could not exist, in the way they are organized today, without being complemented by the technical mentality. The analytical mentality, however, emerges "from the outside" of trials. From its very beginning, it breaks the theoretical and methodological structures of trials, leading the interpretation toward new and unexpected directions. In some circumstances, this approach does lead to contestation, pointing to inaccuracies in clinical research. In this sense, it refuses the accommodating stance of the bioethical approach. The resulting posture can be described by using Bosk's (1999/2008, p. 17) words: we are dealing with a "challenge to medicine," which "[...] was more confrontational in tone, more insistent on structural change, and more focused on the politics of health care than was the bioethics movement."

This challenging stance exists because the analytical mentality has some ideological linkages to "philosophical scepticism." In this tradition, one doubts the basis on which lies the generation of objective and scientific certainties. Knowledge is therefore framed as a human production whose existence must be looked at cautiously, instead of being automatically trusted. Thus, even though the analytical mentality begun to be constituted in the 1980s, it draws, at least partially, on philosophical attitudes proposed by old thinkers such as Michel de Montaigne and David Hume.

As a consequence of these phenomena, the analytical mentality, when it comes to the ethical review of research proposals, strongly opposes the technical mentality. While this latter claims for reviews done by experts, the analytical approach tries to soften the differences between reviewers, arguing that everybody has cognitive limitations and can acquire useful experience at reviewing proposals. The following quotes are aimed to illustrate this debate.

Analytical	Technical
"I'm a psychiatrist. When I'm reading a gastroenterology project, what do I know? You have to admit that even though I'm a physician, I'm not a general practitioner. After thirty years in my specialty, I can no longer think like a haematologist who sees new things every day. So I have to read the structure [...] I look at the protocol's structure [...]." (São Paulo/C2/Physician/04-11)	"*And do you think that somebody who doesn't have a medical background would really have difficulties at analyzing such type of protocol?* I think so. I think there must be someone with expertise in the area to solve some problems pertaining to the scope of the project or some things that are more scientific, you know. I think that a physician must always analyze projects of this nature." (Porto Alegre/C5/Physician/05-11)
"*After these years of work in the committee, what are the results of your being in the committee?* For starters, it has just broadened my knowledge to such an extent that I can't even explain it. It's also made me more confident to be able to participate when there's debate. Okay? So I also have the ability now to say: 'Ya, but you remember that we did that trial two years ago; we found out that...' You understand? So, I can also debate on a level [...]." (Cape Town/C7/Nurse/07-11)	"*So you've never got a protocol from the industry.* I've never got a protocol from the pharmaceutical industry. Thanks God [laughter]. *You don't want to.* I don't want to. *Because of this lack of medical knowledge.* I think, the lack of expertise. The expertise and the medical knowledge [...] I understand neither the research methodology they use (controls, placebos, whether everything is in line with what is usually done in this kind of research) nor the pharmacology and the harms that are likely to be caused to patients, you know [...]." (São Paulo/C3/Social scientist/05-11)
"*So you think that the fact that you don't have a medical background doesn't compromise your analysis.* I think it doesn't. Because, also, if I have doubts, I can always talk to other members in the same way they ask me questions when they have doubts about legislation [...] I see that in some aspects, I have some concerns that they [physicians] don't have, and vice-versa. I think that in certain aspects, they sort of guess, because they have experience, whereas we, as lawyers, are more cautious [...] *For instance.* I think there are situations in which they allow the conduct of studies that may have juridical consequences in the future, involving monetary compensations or even criminal issues, and they don't pay attention to that [...]." (São Paulo/C3/Lawyer/04-11)	"[...] with proper scientific background, you have a sufficient critical view to assess protocols in any field. *So by reading a positive, optimistic protocol, someone without this scientific background would be more strongly influenced.* Absolutely... [pause] both positively and negatively [...] non-physicians frequently refrain the scientific progress because they don't understand [...] I mean, you're not able to exactly understand the justification of things or the relevance of the proposal, you don't have a proper background for that, and then you don't agree [...] I wouldn't even say non-physicians, I'm talking about scientific background [...] *Would you be favourable to committees in which this scientific background is a mandatory prerequisite?* Look, Brazilian regulations are clear and well-defined. You have to have members from several categories, right? However, you're asking me my personal opinion. I think there should be people with an adequate background." (São Paulo/C3/Physician/04-11)

Thus, whereas the technical approach claims for expert reviews, the analytical approach stresses the contributions offered by committee members who lack a scientific background. This is not the only point on which these mentalities disagree. In the following sections, we shall focus on other aspects.

5.3.3 Applying methods

It was seen that both the technical and analytical mentalities pay a special attention to methods advanced in research projects. It is also important to note that committee members, when reviewing proposals, also mobilize their own reviewing methods. On the one hand, reviewers who embrace the technical mentality reinforce, with their review, statistical and clinical procedures used in clinical trials. On the other hand, holders of the analytical mentality strive to apply broader reviewing techniques and perspectives.

As for the technical approach, committee members admit that it is necessary to "measure," so to speak, the distance between proposed methodologies and established scientific standards. Thus, the technical mentality cannot really be exercised without the recognition of binding rules of science.

> "*How would you define bad science?*
> Ah, there are many different ways of defining that. It is a huge question. Bad science is partly science that does not respect the agreed standards of good scientific research. So when I said before there are all kinds of agreements about what constitutes doing good science or what constitutes the production of sort of acceptable new knowledge, so that has to do, in clinical trials or within science, with statistical validity and stuff like that [...]."
> (Cape Town/C7/Bioethicist/08-11)

Thus the technical mentality never ceases to look for standards and patterns. Eventually, the intention is to organize a mighty cognitive enterprise within which

everybody (both clinical researchers and committee members) would be able to control the research process. Hence, the importance of some visual techniques such as graphics, tables and formulas. On the one hand, investigators would derive more controllability from techniques such as scans and computing techniques (Waldby, 2000). On the other hand, committee members would exercise their viewing capacities by means of their ethical (re)views. In this sense, ethics committees would be another incarnation of the "omni-viewing power" created by "technical procedures," to use Certeau's (1990) expressions. On this point, some of Foucault's (1963/1988, 1975/1999) ideas, such as surveillance and panopticism, can help us understand the technical mentality. However, these ideas would rapidly prove much less helpful when we leave the technical approach's domain.

Controllability and precision can be more easily reached with the support of statistical methods. By measuring deviances and "quantifying expectations" (Marschner, 2010, p. 149), statistics has made it possible to deal with the variations verified in global trials. As Marschner explains, it is even possible to anticipate the variations to be displayed by different world regions in a trial. "By studying the expected extent of variation, awareness is created at the outset that can head off the potential for surprises at the end of the study" (Marschner, 2010, p. 155). Thus, when designing (or reviewing) clinical protocols, one can rely on the yardsticks provided by statistics, which as Hacking (1990) puts it, bring about the certainty that regularities can be looked for and eventually identified. One of my interviewees stressed the role of statistics in a clear way:

> "What I see in statistics... It is a toolbox with my tools in there (our mathematical tools) that allow me to convert data into information and then the emphasis is: in an objective way. That is statistics.
>
> *Hm. Okay. So there is no subjective dimension in the design of a protocol, from a statistical point of view.*
>
> No. Not a typical clinical trial, anyway [...] I think the way that statisticians conduct statistics is... You know, statisticians are trying to understand the problem [...] So, automatically, mathematics is there to talk. I follow the rules of mathematics [...] These methods have been tried and trusted for centuries [laughter]."
>
> (Pretoria/C8/Bioscientist/07-11)

For some committee members, the statistical accuracy of a research project is one of the main criteria leading to its approval or refusal. In the hazardous and complex domain of trials, statistical tools seem attractive because they provide researchers and reviewers with guidelines to organize elements and constitute controllable scenarios. This is another step in the long process through which statistical laws acquire a "psychological reality" (Hacking, 1990, p. 205).

This mindset is therefore produced by and derived from the need for control and anticipation.

> "Thus one sees the development of multiple technologies of futurity, most of which seek to 'model' potential futures, notably 'scenario planning' construed as a part of strategic planning that seeks to develop the tools and technologies for imagining potential futures and then managing their consequences" (Lentzos and Rose, 2009, p. 236).

In clinical research, these efforts have already led to the creation of software that simulates studies before their actual conduct in order to foresee difficulties and select methods.

Deeply concerned with standards and objectivity, the technical mentality ends up leaving little space for subjectivity to be expressed. Randomization[70] has turned into a major concern precisely because it is supposed to extract personal choices from the universe of trials. Even though it is sometimes admitted that perfect randomization is an unreachable goal, it is also frequently assumed that a randomly selected sample is a "perfectly made" sample. As claimed before, the modern scientific thought uses experiments to "produce" scenarios from which knowledge can be gleaned. Randomization fits perfectly these ambitions not only because it allows for scientific arrangements to be "made," but also because this production suffers little influence from personal preferences. "Randomization [...] has become part of the logic of induction, reminding us that induction is not just a matter of thinking but of doing" (Hacking, 1990, p. 206). What is important to stress is that the principle of

[70] According to the principle of randomization, research subjects must be distributed *at random* in the placebo group and control group.

randomization has become a central guideline not only for those who design clinical studies but also for some ethics committee members.

> "*But from a mathematical and statistical point of view, what would be an ethical problem?*
>
> [Pause.] An ethical problem would be if you, for example, if you do something wrong in the randomization process [...] If you assign people who are more likely to respond to the drug that you want to win, that would be unethical. You know, interfering with randomization, for example, would be very unethical. And, of course, unblinding would also be very unethical, before the trial is finished, or if your investigator who is to treat these patients gets unblinded in the trial where he is supposed to be blinded.[71] So, basically, it comes to if you, in any way, remove part of the objectivity, then you're compromising the statistics [...]
>
> *So, eventually, subjectivity would be unethical in clinical trials.*
>
> Yes. But subjectivity not in the sense when your assessment is subjective, when you... [pause] when you have to sort of, say, you have to record the colour of my eyes. That is subjective assessment [...] I'm not talking about that kind of subjectivity. I'm talking about subjectivity which favours the outcome for the trial [...]."
>
> (Pretoria/C8/Bioscientist/07-11)

From this point of view, personal hopes and preferences can be reduced by means of clinical trials, "[...] which are seen as providing evidence to balance enthusiasm" (Will, 2010, p. 559). As a consequence of all these ambitions, the technical mentality tends to pay attention to standardized aspects of clinical studies, almost overlooking contextual factors.

> "*Would you have an example of a situation in which the ethical principles are breached?*
>
> [Pause.] To propose a procedure without having adequate theoretical and laboratorial basis for the study to be done. This is the most frequent case.

[71] A "blinded" researcher is the one who does not know which subjects take the candidate drug and which subjects take the placebo.

So the researcher is able to comply with ethical principles when he or she complies with regulations and scientific rules.

No, not only with regulations but certainly with scientific rules.

It has to do with scientific standards.

Absolutely."

(São Paulo/C3/Physician/04-11)

"[...] if you're doing, for instance, an NIH study and there are five sites, five different countries and you're taking blood samples, it is vital that... all the blood samples must be processed in the same lab, otherwise people do different things, in different ways. All has to be done by the same people, in the same lab so that you can analyze your results accurately. You can't... NIH[72] is giving you the money, they're paying, they're saying: 'We've got a specialized lab, please send us the blood.' Some people on this committee will say: 'No, we should be on... capacity-building.'[73] Yes, we should be on capacity-building but we don't have the labs at the moment. So in time to come, they'll build up the lab [...]."

(Cape Town/C7/Lay member/05-11)

In this last example, the interviewee uses technical concerns with research standards in order to counter the communitarian concern about samples and national research infra-structures. Concerned with the issue of standards, committee members voicing strong technical discourses may end up framing research proposals as scientific papers to be assessed in the light of expert knowledge.

"*When you are reading a protocol, do you manage to have an idea of how the actual research is going to happen? I mean, based on the quality of the protocol, is it possible to have an idea of...*

Absolutely. Absolutely [...] a well-written protocol is the one whose structure reflects the structure of the scientific work.

Could a protocol be considered as a previous...

It is a proposal. A well-written proposal is halfway to a well-written article [laughter].

But I mean, in terms of the structure...

[72] The National Institutes of Health (NIH) is a U.S. funding agency.

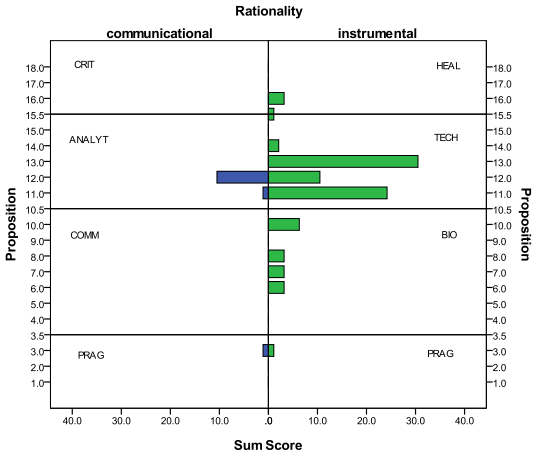
[73] On the South African policy called "capacity-building," see Chapter 4, section 4.2.8.

In terms of the structure. It is the same thing. They can be similar. They can and they must be similar."

(São Paulo/C3/Physician/04-11)

This interviewee has been in the committee for two years. He is a well-known physician and investigator in his therapeutic domain. He conducts academic studies and also participates in trials sponsored by pharma companies as principal investigator. The following *discourse graphic* derived from his interview.

Figure 5.3 – Discourse graphic n. 18



This discourse is decisively dominated by two groups of claims: first, there is a technical approach to ethics committees (TECH13); second, the idea of scientific knowledge and its standards (TECH11). It is worth noting the ideological support from some bioethical claims, as well as the almost complete absence of claims at the communicational side.

More than any other mentality, the technical approach praises the idea of evidence, which is conceived as the conclusion deriving from well-reasoned procedures and concepts. Eventually, evidence, which is a human creation, turns into a force that no human being can oppose. As Arendt (1963) claimed, mathematical evidence, insofar as it faces people with its undeniable force, may become as powerful as divine forces. Every mathematical statement (such as two and two is four) "[...] is rooted in the physical structure of the human brain, and therefore is 'irresistible'" (Arendt, 1963, p. 194).

In contrast to this mindset, the *analytical mentality* seems to favour moral discourse, which "[...] is indeed a statement of reason and even a reasoned statement which stands in need of agreement" (Arendt, 1963, p. 194). Thus, the reviewing methods marshalled by committee members holding this approach are frequently flexible and tentative. It is as though holders of the analytical mentality were striving to build up new models of ethical review. During my fieldwork, I was intrigued by the

fact that only when this approach emerged in the interviews, members displayed very deep concerns with the intricacies and details of research proposals.

> "*But do you think that when you're reviewing an industrial protocol, you have a different stance toward the protocol?*
> No, if the protocol involves the test of a new medicine, I'll follow the procedures I described to you, I'll look at Medline, I'll be very careful, especially if the medicine has not been approved in the country, you know [...]."
> (São Paulo/C3/Social scientist/05-11)

> "*Do you think there is any part of the protocol that needs to be read more carefully?*
> Oh, the methodology [...] The methodology says how you're going to approach, how you're going to do, whether you're going to collect blood or not, how you're going to administer, how... I think I'm learning this part [...] When I'm not sure about something they say, especially statistical points... So if they use statistical terms and I don't know whether that exists, I look on the internet and find whether that statistical method exists, in order to know if they're not proposing something that doesn't exist [laughter]... Because, I mean, as I don't know everything, you know (I'm doing a basic course on that), so I mean, when they propose: 'Oh, we are going to apply the tests x, y and z,' and I don't know whether the tests exist, I look on the internet to know whether the tests really exist [...] They describe how the test is and I do the comparison to see whether what is said on the internet is said on the protocol [...]."
> (São Paulo/C3/Bioscientist/05-11)

It is indeed surprising that such carefulness was manifested in so few interviews during my fieldwork. Once ethics committees are supposed to *analyze* research proposals, one might suppose that more interviewees would display this kind of *analytical* precautions. In the last example, the interviewee has even been careful enough to attend a course on statistics. Thus we see that the review of projects imply many kinds of knowledge and some cognitive gaps that some members seem to be willing to overcome. On this point, the internet can be a useful tool. Indeed, in the examples quoted above, the acquisition of information online is mentioned, and one interviewee has even referred to a medical database (Medline). However, analytical

claims proved rare during my fieldwork, as can be seen in the *discourse boxplots* presented in Figure 4.2, page 110.

Frequently, the analytical mentality tries to look at clinical trials in a historical perspective and establish connections between past examples and current research practices. Whereas the holders of other mentalities mention only clinical studies they reviewed, holders of the analytical approach often refer to recent studies that have become classic references in the domain of clinical research. Another typical analytical attitude is the reference to texts and studies on clinical trials, mobilized in order to support one's claims.

> "*In your opinion, what is the main goal of clinical research?*
> [...] it is a very wide term [...] The problem is, if you see it from a drug companies' point of view, they are doing research. They're doing it in a clinical setting, therefore is clinical research. But the aim is to promote that drug. And I mean, there are lots of examples where things have been twisted slightly. I mean, you only have to look at Tamiflu[74] [...] They've come up with the results but they hide their way. So you've got to be careful [...]."
> (Cape Town/C6/Physician/08-11)

Holders of the analytical mentality seem to be aware of details that go beyond their everyday experience in the committee. One example comes from the previous quote, in which the interviewee referred to the clinical trial that led to the approval of a medicine recommended for swine-flu.

There is a claim moving smoothly from the pragmatic, through the communitarian, and into the analytical approach: clinical trials are decisively informed by the industry's financial interests. In the analytical mentality this concern, in addition to its moral hues, is covered by social concerns. Moreover, one tries to gather arguments and information with which these financial interests can be unmasked. One example is the study conducted by Juni and collaborators (2004, p. 2024), in which methodological frailties of a clinical study were attributed to the company's economic motivations: "Meta-regression analysis indicated that the funding source largely

[74] Tamiflu is a Roche's medicine against influenza. In 2009, after an international outbreak of the so-called swine-flu, the US Food and Drug Administration recommended its use for this disease.

explained between-study heterogeneity, with studies funded by Merck indicating larger cardioprotective effects of naproxen […]."

As this quote shows, holders of the analytical mentality are not refusing statistical, clinical, scientific and argumentative tools provided by the technical mentality. On the contrary, such tools are frequently mobilized by analysts as well. However, this analytical use is realized not to furnish the domain of clinical research (like in the technical mentality) but in order to deconstruct clinical research, identifying its composing elements and rearranging them into a new order.[75] In a sense, analysis amounts to ideological betrayal. We are referring to what Certeau (1990, p. 58) described as "analytical capacity," which creates:

> "[...] a playing space for *ways of using* the binding order of place and language. Without leaving the position where it needs to live and which dictates certain rules, it establishes plurality and creativity. Through a mediating art, it derives unforeseen effects" (Certeau, 1990, p. 51-52).

In clinical research, the main purpose of this "mediating art" is to go beyond clinical issues, unravelling the social aspects of trials. Thus, one example of analytical ambition would be: "One goal of my research is to understand how wider ethnographic contexts inform the design and operation of clinical trials" (Petryna, 2006, p. 57 - note 7). Social concerns were also voiced by some of my interviewees.

> "*So you don't consider the consent form as the part you have to focus on.*
> I think it is a part that one has necessarily to pay attention to, but I think there are other very important issues, especially in the methodological part [...] I think my perspective is more sociological or anthropological. The consent form is the relation to *one* subject [...] but the ethical dimension of research in terms of social aspects, social implications, goes beyond this individual dimension [...] The sample size, the place where the interviews or the study will be conducted, the time when it will be undertaken, whether it will involve patients and their relatives, the issue of confidentiality not of the research subject but pertaining to the relations to other research subjects, I think those are social questions of research that go beyond this

[75] Etymologically, an "analysis" is a "break-up."

> exclusive bilateral dimension (researcher and research subject), you know. And the consent form is an individual instrument, because it focuses on the individual. And I think the ethical dimension involves the individual in a broader social context, which is not addressed by the consent form alone [...]."
>
> (São Paulo/C3/Social scientist/05-11)

Thus, the analytical mentality struggles to identify social relations. To describe its rationale, we can repeat Becker's (1996, "Why do we think there is a difference?") words: "The point is not to prove, beyond doubt, the existence of particular relationships so much as to describe a system of relationships, to show how things hang together in a web of mutual influence or support or interdependence [...]."

From this point of view, there emerge political concerns, in the sense that clinical trials would be "[…] a key technique […] for mediating between pharmaceutical companies, clinicians, governments and the public" (Will and Moreira, 2010, p. 1). Once again, the analytical mentality confronts the technical mentality by doubting or rejecting the assumption that clinical researchers and committee members can be carriers of objectivity. Science and politics would thus be strongly intertwined (Jasanoff, 1990, Petryna, 2009).

Even though the mentalities addressed here come to different or even opposite conclusions, they are both informed by precise ideas and shaped by identifiable reviewing methods. Whereas the technical mentality accepts the rationale and tools mobilized in the design of clinical studies (such as randomization, statistics and placebos), the analytical rationale frame these tools as objects of study, which must be scrutinized in the light of social interests and relations. Here, we are completely immersed into the foreground knowledge, where there is little space for intuitive and emotional claims to impose themselves as main arguments. Obviously, the ideological differences between the two approaches also define two discordant ways to look at regulations and regulatory agencies, as we shall see subsequently.

5.3.4 Views about regulations

In the *analytical* (like the *communitarian*) *mentality* there is much scepticism about the regulations' capacity to circumvent problems in clinical trials. What is more, the global harmonization undergone by clinical guidelines tends to be seen as a threat to the comprehension of relevant differences. For example, Timmermans and Epstein (2010, p. 70), in a typical analytical vein, pointed out the problem that "[…] we place standards and standardization in the foreground as ubiquitous but underestimated phenomena that help regulate and calibrate social life by rendering the modern world equivalent across cultures, time, and geography."

In addition, holders of this approach also scrutinize research guidelines, pointing to weaknesses and flaws, like McGoey and Jackson (2009) did with UK's pharmaceutical rules. Another example comes from Angell (2005), who analyzed the Food and Drugs Admistration's guidelines, stressing that drugs are considered to be good enough when compared to placebos, instead of other actual drugs.

Here we are not very far from the *critical mentality*, for which problems and flaws are what really matters. Nevertheless, as claimed before, the *analytical mentality* still tries to propose alternative perspectives by working with the current "rules of the game." This is probably why one of my interviewees, who voiced an analytical discourse, managed to discover an unsuspected analytical dimension in current guidelines:

> "*So are you somehow concerned about the fact that there are many foreign companies conducting clinical trials in South Africa?*
>
> Ah... No. Oh, yes and no. No because we still have a very good regulatory system. Trials have to go through ethics committees [...] I cannot answer you whether in fact all the ethics committees are as rigorous as they should be. That is another issue. But we have a very... We have a format which ensures that we keep a reasonable control on what is going on in this country [...] So I wouldn't be concerned about drug companies doing any worse research here than they do in Europe or the States [...]
>
> *Because they comply with global standards.*

> They... Yeah. Most of the trials which are done in this country are multicentre. So the protocol comes to us from whichever companies develop it, the big Russel, Pfizer or whoever."
> (Cape Town/C6/Physician/08-11)

Probably, this interviewee extended his own "rigorous" (analytical) ways of reading proposals to the whole reviewing system, which is based on a regulatory system that he considers as "very good." However, this kind of positive (or optimist) perspective is quite rare in the analytical mentality. For instance, Petryna detected, in the European Union guidelines, loopholes with which there can be a chain of outsourcing operations in clinical trials. In this way, "[...] responsibility for the conduct of the trial and for insurance, along with civil liability, is continuously transferred to third parties who would in practice prove difficult to track" (Petryna, 2009, p. 107).

In its turn, the *technical mentality* stresses the idea of progress. Clinical research would be submitted to improving trends that include regulatory frameworks. Eventually, people admit an overall advancement, in which researchers, committees and regulations progress together, adjusting to each other.

> "*It seems to me that sometimes researchers are more reluctant towards committees because they think that committees may refrain the research process.*
> Look, this discussion may exist, right? But with time, what happens? The whole system gets adjusted to the regulatory framework. If we think about it, we're talking about a framework that is not so old, including Brazil. We're talking about a bit more than fifteen years. It is the time we've actually had an adequate definition and regulation for ethics committees. That caused an initial difficulty in terms of adjustment from some people, of course. Today, I think this is much consolidated."
> (São Paulo/C3/Physician/04-11)

Thus researchers, regulations and committees are thought of as a single system of slow consolidation. From this point of view, there is the subtle, albeit potent, underlying idea that nowadays, clinical trials tend to be less problematic than past studies.

"We've also developed the pharmaceutical industry to such a large extent... You know, something that was often lacking and today anybody follows the correct route is, you know, you for example say: 'A sample size of this magnitude [knock on the table] detects such a difference.' But that difference may or may not be clinically relevant [...] But today, you know, it is seldom that a problem with the sample size takes place in protocols [...]."
(Pretoria/C8/Bioscientist/07-11)

"[...] people sometimes have... I wouldn't say preconceptions, you know, but a view that is critical...
Cautious.
Cautious about certain protocols [...] I think this belongs to the past [...] I have not heard about new examples of multinational companies exploiting vulnerable people."
(Porto Alegre/C5/Lawyer/05-11)

In this way, the technical mentality tends to admit that many ethical problems in clinical research have been sorted out. This mindset has a corollary: considering the scientific and ethical accuracy of current clinical studies, the heavy bureaucracy of ethics committees, as well as the inconsistencies between the operations of different committees, may end up delaying or stifling the conduct of important studies (Harries et al., 1994, Meade, 1994, Ahmed and Nicholson, 1996, Redshaw et al., 1996). Equally, national regulations may be seen as too stringent, threatening further scientific developments. Yusuf (2010), for instance, emphatically claimed that "over-regulation" has been hampering the conduct of many beneficial trials.

"*As a researcher, do you agree that Brazil might improve its performance in terms of the ethical review turnaround time?*
Absolutely. However, look, it *might* improve. Nevertheless, you have today a regulatory framework that, one the one hand, is very accurate, and its structure, on the other hand, does lead to barriers and long waiting times. As a consequence, Brazil has difficulties at being in the frontline of clinical research at the international level."
(São Paulo/C3/Physician/04-11)

"[...] I do sometimes get... I mean, not very often, but there is a certain impression I get from some physicians in South Africa about the idea of clinical drug trials: 'They must all be really bad, especially big companies; big companies must be doing things... doing harm to patients in order to make profits.' I think there is very little understanding on how those clinical trials are put together and why and what goes into putting them together. And the strictness of current regulations, which actually make those things quite difficult. And I think there's far less... there are far fewer ethical issues with trials than there were perhaps ten years ago. I'm not saying they don't exist [...], but I think the assumption is always, in our academic setting, that: 'We've got to look very carefully at those trials because they must be doing some harm to the patients; or the investigators are doing it for the wrong motive [...] they must have a money motive for doing the trial and not a science motive' [...]

Okay, so the review is biased.

I have wondered about that. It is not something I would say 'absolutely' but I do suspect that there is an element of it. And from the laypeople, certainly, there is a big anti-pharmaceutical feeling. And our lay members have, sometimes, big comments [in the meetings] that reflect an inherent bias [...]."

(Cape Town/C6/Physician/06-11)

It can be said that in this last quote, the interviewee is dissatisfied with stances advanced in all *communicative mentalities.* Indeed, the suspicious attitude she talked about stems from the *pragmatic mentality*, being reproduced and reinforced by the *communitarian* and *analytical mentalities.* On the other hand, pragmatic claims according to which financial interests come to play in clinical research tend to be "tamed" and unproblematized by the *bioethical* and *technical* mentalities.

By observing the quotes presented throughout this chapter, it is perhaps easy to see that we are dealing with a political debate whose basic opposing claims can be summarized as follows:

- Technical claim: Clinical research, and especially the accurate trials sponsored by pharma companies, promotes scientific progress and should be assessed by specialists based in ethics committees and government agencies

- Analytical claim: Clinical research, and especially the interested trials sponsored by pharma companies, may contain distortions and flaws, requiring, from ethics committees and government agencies, a large discussion involving people with diverse backgrounds

Thus, the technical and analytical mentalities offer not only two divergent philosophical stances but also two divergent recipes for the social discussion about clinical trials. In order to really grasp the nature of such disagreement, it is important to verify the linkages between these two mentalities and pragmatic concerns.

5.3.5 Relations to background knowledge

As claimed in Chapter 4, the *bioethical* and *communitarian mentalities* have smooth and regular contacts to the *background knowledge.* At the level of the *technical* and *analytical mentalities,* however, these contacts depend on a series of ideological mediations. In order to understand these processes, it is worth considering the following *discourse graphics.*

Analytical	Technical

Figure 5.4 – Discourse graphic n. 6

(São Paulo/C3/Social scientist/05-11)

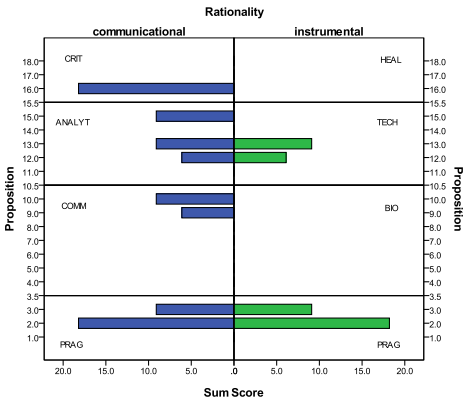
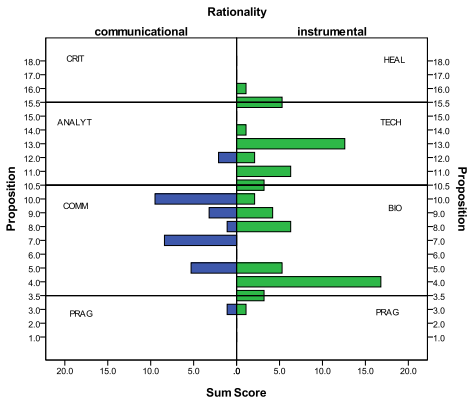


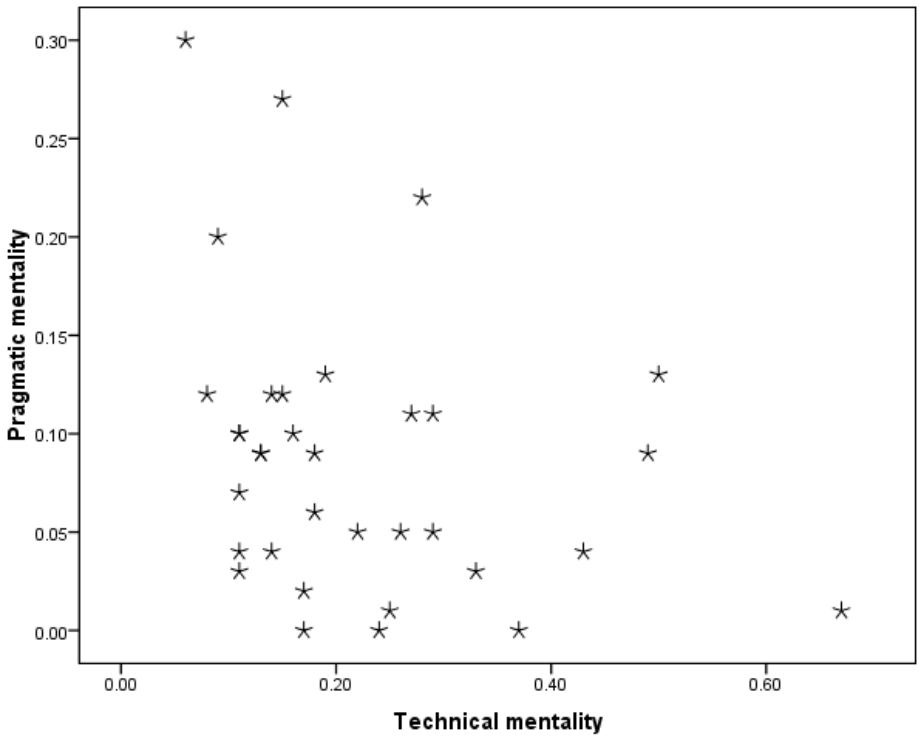
Figure 5.5 – Discourse graphic n. 17

(Cape Town/C6/Physician/08-11)



In Figure 5.5 (which depicts a technical discourse strongly based on bioethical claims), pragmatic concerns play a very minor role. In Figure 5.4 (which depicts a discourse that can be described as analytical/critical), pragmatic claims are obviously much more important. By looking at these graphics, as well as others derived from other interviews (some of them presented previously), I got intrigued by the weakness (or complete lack) of pragmatic claims in technical discourses. The following scatter dot (derived from my 34 strong interviews) gives us another image of this phenomenon.

Figure 5.6 –Scatter dot: pragmatic and technical mentalities



This graphic shows us the relation between the proportion of pragmatic and technical claims (each interviewee being represented by one star). We can see that no interviewee voiced high proportions of both technical and pragmatic claims. Even though the visual correlation is not very clear, there seems to be a tendency for pragmatic claims to decrease when technical claims increase. In order to assess this correlation, I divided the interviewees into three groups:

1. Low level of pragmatic claims: pragmatic scores ranging from 0 to 0.05
2. Medium level: scores from 0.06 to 0.15
3. High level: 0.16 or higher

Thus, a discourse is considered to convey a high level of pragmatic claims when at least 16% of the interviewee's claims expressed pragmatic concerns. Finally, using a

statistical test[76] to correlate the proportion of technical claims and the levels of pragmatic claims, I verified a negative coefficient of 0.35, which according to Cohen (1988), indicates a medium correlation. Thus, whenever the proportion of technical claims increases, the proportion of pragmatic claims decreases at a medium rate.[77] The coefficient of determination is of 0.12, meaning that 12% of the reduction in pragmatic claims is explained by the increase in technical claims.

The conclusion is: holders of the technical mentality seem to abandon their ideological connections to the *background knowledge,* which as explained in Chapter 3, is composed by basic assumptions largely shared within society. It is as though committee members, by embracing the technical mentality, were sacrificing immediate and simple assumptions for the sake of scientific *codes.* In this way, simple ideas of the *background knowledge*, such as "interest," lose their taken-for-granted nature in order to fit into theoretical structures. Thus, "interest," rather than being an obvious notion that is immediately understood by every citizen, becomes a concept in need of definition. This is what happens, for example, when one claims that "[...] interests can be systematically related to the biasing of scientific knowledge" (Abraham, 1993, p. 389).

From a common-sense mindset in which no clarification or definition is needed (*background knowledge*), one goes towards an ideological universe in which theoretical definition and clarification is everything that really matters (technical mentality). We are dealing with a process that Arendt described by speaking of "introspection" and "loss of common sense."

> "[...] it is the playing of the mind with itself, which comes to pass when the mind is shut off from all reality and 'senses' only itself […] Here the old definition of man as an *animal rationale* acquires a terrible precision: deprived of the sense through which man's five animal senses are fitted into a world common to all men, human beings are indeed no more than animals who are able to reason […]" (Arendt, 1958/1998, p. 284).

[76] Spearman correlation, which is used for non-normally distributed data.
[77] The associated p value is of 0.03.

The over-reliance on statistical methods fosters the process, for in the technical mentality, the formulation of ideas is no longer based on immediate evidence that one grasps in discourses, actions, newspapers, daily conversations, and so on. In clinical research, ideas stem from theoretical models whose *ultima ratio* lies on the statistical laws themselves. According to Sismondo (2010, p. 639), statistical evidence does not depend on visible elements to emerge, and this is why "[...] what is more fundamental is invisible." In the technical mentality, therefore, the "social evaporation of the tangible" (Arendt, 1958/1998, p. 69-70) reaches high degrees.

In the following table, we can look at the aforementioned three levels of pragmatic claims according to professional backgrounds.

Table 5.1 – Proportion of pragmatic claims according to professional background

		Background				TOTAL[78]
		Lay members, nurses & social workers	Social scientists	Bioethicists & lawyers	Physicians and bioscientists	
Proportion of pragmatic claims	Low (0 - 0.5)	1	1	4	8	14
	Medium (0.06 - 0.24)	5	3	3	5	16
	High (0.25 or more)	0	3	1	0	4
TOTAL		6	7	8	13	34

[78] In this table, I am including only "strong interviews," that is, the interviews that lasted 30 minutes or more.

As this table shows, lay members, nurses and social workers did not voice high levels of pragmatic claims. They are rather concentrated at the medium level, a circumstance that I try to explain in the next section. Apart from one bioethicist, only social scientists appeared in the high proportion group. This circumstance is probably due to the high levels of communitarian concerns of social scientists,[79] generally defining an important attachment to the *background knowledge*. Bioethicists and lawyers are concentrated at the low and medium levels. The same phenomenon is verified for physicians and bioscientists. Thus, this table confirms the tendency for cutting down on pragmatic concerns when one acquires a background in biomedical sciences.[80]

As we have seen, the analytical mentality has managed to affirm itself by promoting some "lay invasions" of medicine. However, if this process has been somewhat successful in clinical trials and ethics committees, the domain of basic science continues to be much closed to lay eyes. Epstein (1996) noted this phenomenon in the mid-1990s and it is possible to say that things have not changed since then. In this way, scientists managed to preserve a set of procedures and concepts that protect their expertise and legitimize their *codes.* In this realm, scientific hypotheses must be tested with scientific methods, looked at in the light of scientific concepts and lead to scientific conclusions expressed scientifically. By means of such metalinguistic operations, *background knowledge* is lost and one is finally thrown "[...] into the prison of his own mind, into the limitations of patterns he himself created" (Arendt, 1958/1998, p. 288).

As a consequence, holders of the technical mentality, when addressing social issues, seem to have difficulties at mobilizing concrete examples and tend to advance very unspecific claims. Eventually, the benefits of clinical research are said to be gleaned not by particular individuals or groups but by categories such as men or humankind.

[79] See Chapter 4, section 4.2.8.

[80] In her study about an Aids-related clinical study, Mueller MUELLER, M.-R. 1997. Science versus care: physicians, nurses, and the dilemma of clinical research. *In:* ELSTON, M. A. (ed.) *The sociology of medical science & technology.* Oxford: Blackwell. had already noted that physicians tended to overlook personal aspects of trials, wishing to have rapid access to patients' clinical information and claiming that "[...] data belonged to the researchers and could therefore be used to advance the goals of clinical science [...]."

"*In your opinion, what is the main goal of clinical research?*

I think... Actually, when you begin to research things, that will benefit humankind... I think a study leaves that world and go to a much bigger world. It can begin in a small space, with that researcher, with that group of subjects, but I think this information can be brought to the whole world and be used by humankind. I think many studies have this goal. By the way, many start in a very small world and they grow until the moment in which somebody who is at the other side of the world has access to something like that [...]

But when you say that it leaves a small space and reaches a bigger world... What goes to the world?

The result, you know. The result [...] People will have access to it. Humankind will have access to it. For good things, I think, for changing, for advancing. I see clinical research as development.

And the result of research would be a product, a notion...

Oh, I think it is everything. It is a product, it is a notion. I think many times it is a new way to see something [...]."

(São Paulo/C2/Nurse/04-11)

In contrast to this abstract discourse, the *analytical* (like the *communitarian*) *mentality* seeks particularities and concrete examples. Its main concern is to denounce practices that diffuse homogenising rationales and "[...] turn amorphous, heterogeneous experience into a calculable problem" (Lakoff, 2007, p. 58). In this effort, the analytical approach has been confronting not only the *technical mentality* (and its abstract scientific concepts) but also the *bioethical mentality* (and its general ethical principles). Thus a typical analytical claim is: "Rather than focusing on normative theory of ethics and ideal conditions, I maintain the importance of apprehending the norms that are being propagated and how they are being reconstructed in actual and diverse conditions" (Petryna, 2006, p. 55).

Philosophically speaking, one could draw a distinction between analysts and technicians. On the one hand, the technical mentality (held by technicians) proposes a metalanguage that speaks in the science's name, using scientific concepts. In this way, a set of immediate and widespread ideas is no longer essential and, therefore, a universe is built up in which "[...] reality and human reason have parted company" (Arendt, 1958/1998, p. 300).

On the other hand, the analytical mentality (held by analysts) stays in touch with *background knowledge* (via communitarian mentality). Immediate, common-sense claims (such as "clinical trials imply financial interests") do not disappear from the core of analytical discourses in their process of constructing a *foreground* theory. Therefore, *background* and *foreground knowledge,* ideological periphery and core, remain connected, enabling the emergence of a "communicative flow," to use Habermas' (1996) expression. To be sure, discourses voiced by analysts are sometimes very sophisticated and even hermetic. Yet this complexity does not tend to form an enclosed world, for there are strong attachments to *background knowledge.* As a consequence, one can say that compared to the technical mentality*,* the analytical approach has been more successful at preserving what Habermas (1996, p. 360) called "[...] the general comprehensibility of everyday communicative practice."

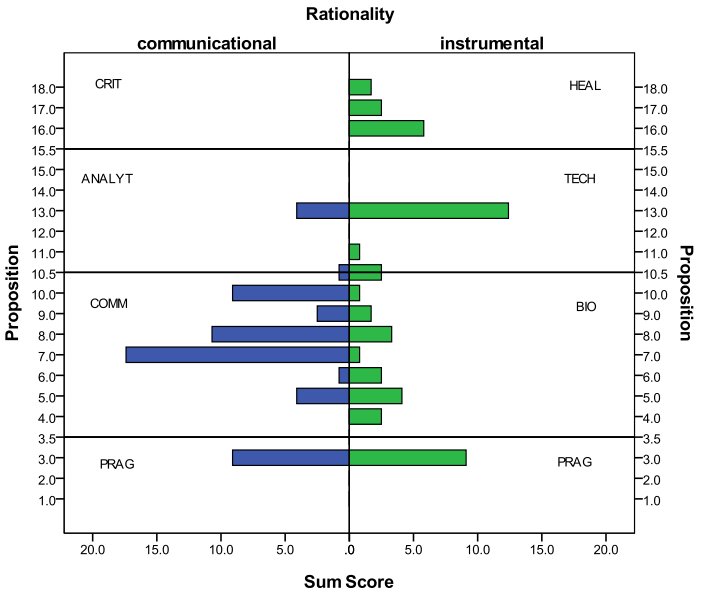
In the following section, we focus on a particular relation between the *technical* and *communitarian* mentalities.

5.3.6 Mental colonization and mental inversion

In the previous section, it was argued that committee members who have a biomedical background are more likely to voice technical claims. This does not mean, however, that other categories of members do not have access to the technical mentality*.* In my fieldwork, technical claims were voiced not only by physicians, pharmacists, biologists and so on, but also (albeit in lower degrees) by lawyers, bioethicists, social scientists, nurses and lay members. In these cases, though, technical claims assume two particular features. Firstly, they tend to constitute a group of ancillary claims in a *discourse* dominated by other mentalities*.* Secondly, they seem to be "colonizing" one's mental life. In order to study this second phenomenon, let us consider the following *discourse graphic.*

Figure 5.7 – Discourse graphic n. 10

(Cape Town/C7/Lay member/05-11)



This is one of the two lay members interviewed in my fieldwork.[81] As the graphic shows, this discourse is dominated by communitarian claims but there is a group of technical claims (TECH13) that seems strangely important here. This group of claims stresses the scientific role played by ethics committees and the importance of scientific expertise in ethical review. This is one example of a situation in which the interviewee advanced these ideas:

> "*But is there any situation [in the meetings] in which you don't feel confident to ask a question or to give your opinion?*
>
> [Immediate reply.] Oh, yes, no, no, then I don't. No, no. Especially when it comes to things like drugs and things like that. I'll review... I'll do a drug protocol *review*, but I'll state that I don't know... that I'm not qualified to comment on the drug [...]."

[81] The *discourse graphic* derived from the interview with the other lay member is presented in Chapter 4, Figure 4.7.

Holders of the communitarian mentality, regardless of their background, proved very likely to advance this sort of claim. I present two more examples:

> "*Is it more difficult to review clinical trials [compared to academic studies]?*
> I think for a non-medical person. I mean, I've got nursing, I've got some of the background, but things like your pharmacokinetics and your pharmacodynamics, I'm not that clued upon it because in nursing, of course, we don't do it in that depth. So I wouldn't know what kind of effect certain drugs would have if it is used in this particular way, you know. So those kinds of things I can't judge, but I would look at the ethics of it [...] Things like the insurance documents, the budgets and those kind of things, I would give an opinion [...]."
> (Cape Town/C6/Nurse/08-11)

> "*Is there any situation or any type of discussion [in the meeting] in which you don't feel very confident to advance your opinion?*
> Yeah. I mean, I think it is... you know... Well, it is not... it is not really confidence so much as lacking expertise [...]
> *Ah, okay. Okay, but do you think that the view of doctors tends to predominate because they have this medical expertise?*
> Hm... [Pause.] Yes, it does. Hm... You know, I don't think it only predominates, I think it is sort of taken for granted. You know, that is the taken-for-granted opinion, and it is often right because they know the medical science and it does become difficult to challenge that, at times. Yeah."
> (Cape Town/C7/Social scientist/07-11)

What is interesting is that this point was insistently made in these interviewees' *discourses*, as the following table shows.

Table 5.2 – Committee members holding the communitarian mentality: number of times in which interviewees recognized the physicians' knowledge advantages

Interviewee	Occurrence of the claim	Length of the interview recording
(Cape Town/C7/Lay member/05-11)	4	53min08s
(Cape Town/C7/Anthropologist/07-11)	3	55min30s
(Cape Town/C6/Nurse/08-11)	3	63min12s
(São Paulo/C3/Lay member/05-11)	3	33min25s
(São Paulo/C2/Social scientist/05-11)	2	49min42s
(Porto Alegre/C5/Lawyer/05-11)	2	26min04s
(Cape Town/C7/Anthropologist/07-11)	1	55min36s
(Porto Alegre/C5/Psychologist/05-11)	1	44min57s
(Cape Town/C7/Anthropologist/08-11)	0	58min14s
(Brasília/C4/Physician/04-11)	0	25min03s

This table is based on the ten interviews in which discourses were dominated by the communitarian mentality.[82] The first committee member (whose interview was the basis for the *discourse graphic* shown above) spontaneously voiced this claim four times, at different moments of a recording that lasted 53 minutes. There were only two interviewees (holders of the communitarian approach) who did not make this point. Thus, there is a technical claim punctuating communitarian *discourses*, like a background noise.

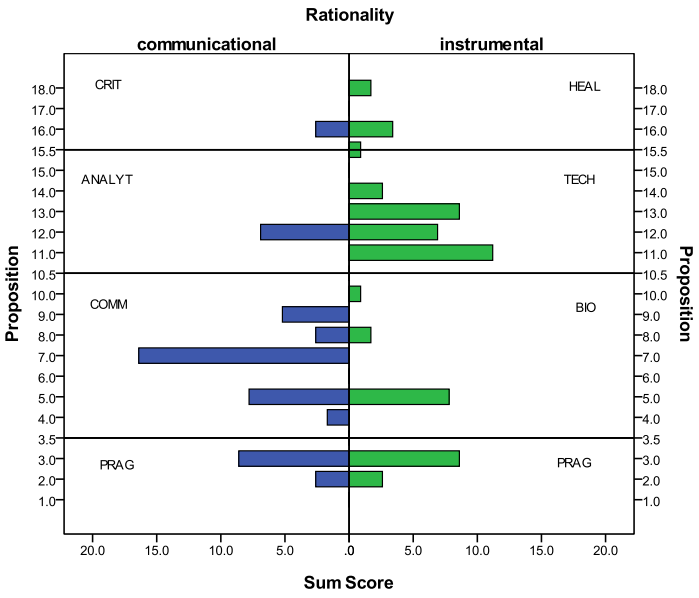
In the example analyzed, one particular group of technical claims was focused on (TECH13). However, there are other claims that can be taken from the technical

[82] I am considering only "strong interviews," that is, interviews that lasted 30 minutes or more.

mentality in order to reverberate in communitarian discourses. The following *discourse graphic* provides us with an example.

Figure 5.8 – Discourse graphic n. 32

(São Paulo/C2/Social scientist/05-11)



This communitarian discourse, voiced by a social scientist, is permeated not only by TECH13 but also by TECH12 (which stresses the importance of methodologies in the ethical review) and TECH11 (which frames clinical research as an enterprise aimed to enhance scientific knowledge). Holders of the communitarian mentality can also mobilize the technical idea that ethical analyses done by physicians are more important than the analyses done by other members, or the idea that ethics committees aim to enhance research progress.

"*Do you think there is any type of protocol that deserves more attention?*

Yes, there is. These are the protocols that involve surgeries, medicines, devices, shifts of medicines, hospitalizations. For me, this is a bit complicated. So these protocols go to specialists in the topic. I avoid getting it because, as I told you, I'm not a physician,

so who am I to analyze the patients... Do you understand? So I avoid these things. Yes, yes, there are protocols that are more difficult, others are easier."

(São Paulo/C3/Lay member/05-11)

"*And in your opinion, what is the main goal of an ethics committee?*

The main goal is to prevent harm but also to facilitate research. It is a balance between allowing good research to go on and to protect vulnerable groups and people, to see that there is no harm."

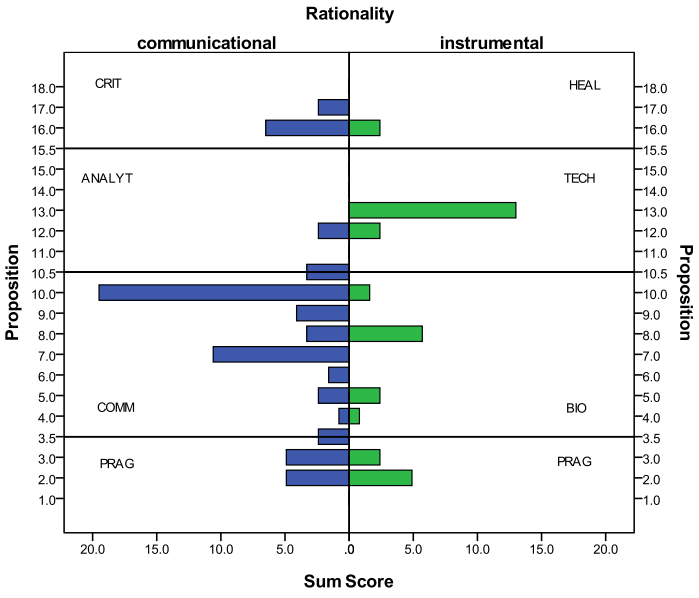
(Cape Town/C7/Anthropologist/07-11)

In this last example, there is a telling combination between a communitarian concern (harm to research participants) and a technical idea (research progress).

In my discourse graphics, this sort of claims was generally grouped into TECH13, which thus tend to catch the eye like an "apparition," as the following example illustrates.[83]

Figure 5.9 – Discourse graphic n. 15

(Cape Town/C6/Nurse/08-11)



[83] Other examples can be seen in Chapter 4, Figure 4.5 and 4.7, as well as Chapter 6, Figure 6.6.

I am considering that these interviewees are advancing technical claims. However, this is a "passive" way to use the technical mentality. For true holders of the technical approach, who generally are physicians and bioscientists, these claims assume an active vein, in terms of "we are the most competent people to analyze clinical trials; we know it." For holders of the communitarian mentality, who frequently are social scientists and lay members, the claim is passively advanced, in terms of "they are the people with expertise to analyze clinical trials; we recognize it."

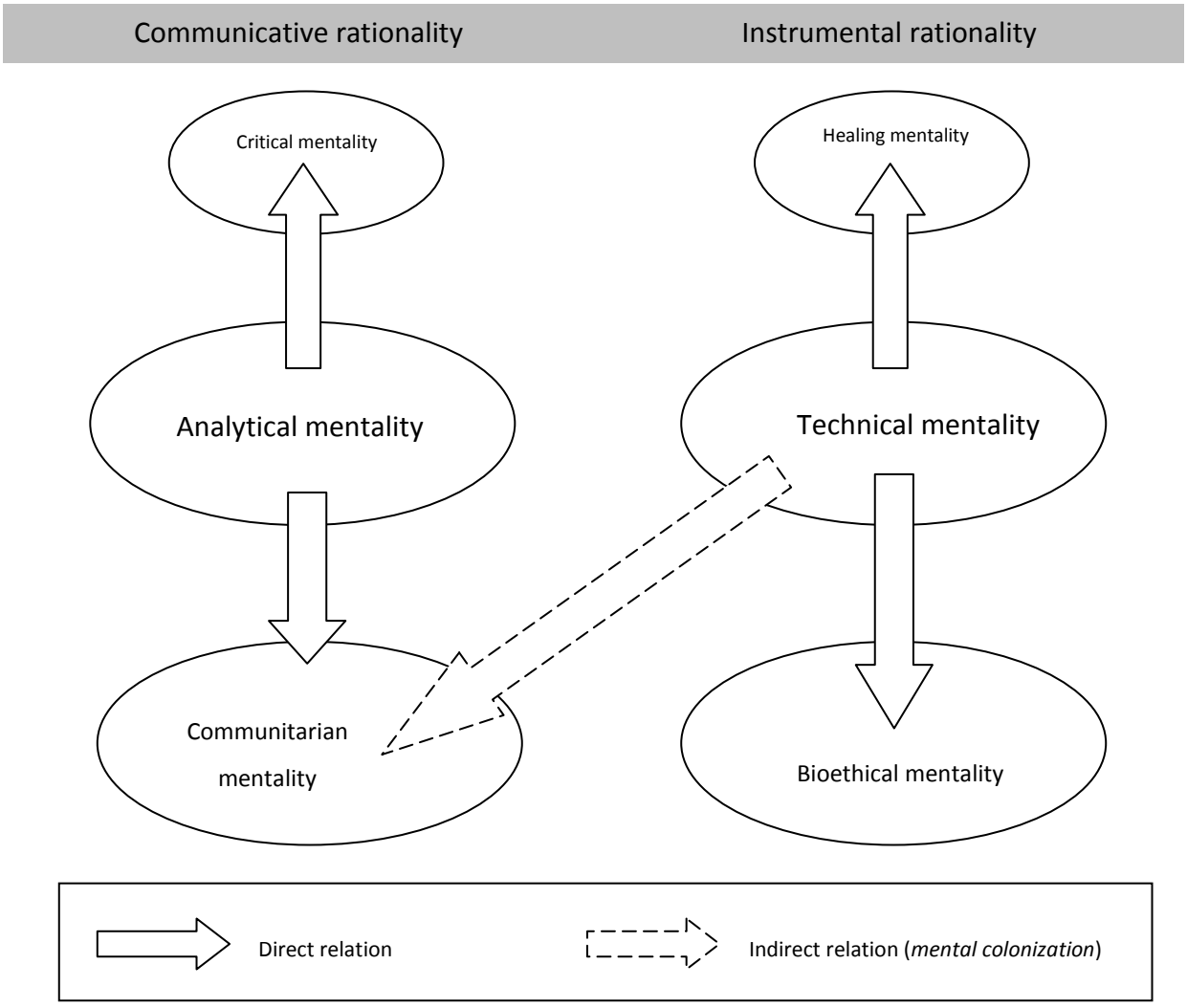
We can speak of *mental inversion,* in the sense that in communitarian discourses*,* some technical claims are adopted and begin to punctuate the discourse. Moreover, these claims are simply recognized, without discussion, and become taken-for-granted ideas. Thus these claims start playing a role that in other mentalities, is played by the *background knowledge.* In other words, the technical mentality becomes the *background knowledge* of committee members who embrace the communitarian mentality*.* They are willing to discuss and develop pragmatic and communitarian concerns, whereas the notions coming from the technical approach remain hidden and protected from debate. *Background knowledge* turns into *foreground knowledge*, and vice-versa. It is as though, when looking at a *discourse graphic* depicting a communitarian discourse, we were seeing it upside-down. Hence, the idea of *mental inversion,* a phenomenon that has an important political implication.

As we have seen in this chapter,[84] the analytical mentality opposes technical claims with the idea that everybody is qualified for reviewing research proposals, insofar as even physicians have their knowledge limitations. The communitarian mentality, when faced by technical claims, proves to be more docile, recognizing the knowledge primacy of physicians and bioscientists. What is more, this recognition (by means of *mental inversions*) becomes a sort of *background knowledge* and therefore acquires an irresistible force. This is the phenomenon of *mental colonization:* some claims move from the technical into the communitarian mentality; as a consequence, even if the technical mentality does not manage to impose its force in a direct way, it can always exercise an indirect influence upon committee members who embrace the communitarian mentality*.*

[84] Section 5.3.2.

On the one hand, the communitarian approach does not imply any type of practical and political project, as seen in Chapter 4. On the other hand, we have seen in this chapter that the technical mentality holds a very strong and precise political discourse, which foregrounds the importance of promoting research progress and supporting global clinical trials. The phenomenon of mental colonization enables the diffusion of this political project from the technical mentality to the holders of the communitarian mentality. In other words, technical notions come to fill the political gap that characterizes the communitarian approach. The following figure summarizes these politico-ideological relations.

Figure 5.10 – Politico-ideological influences between different mentalities

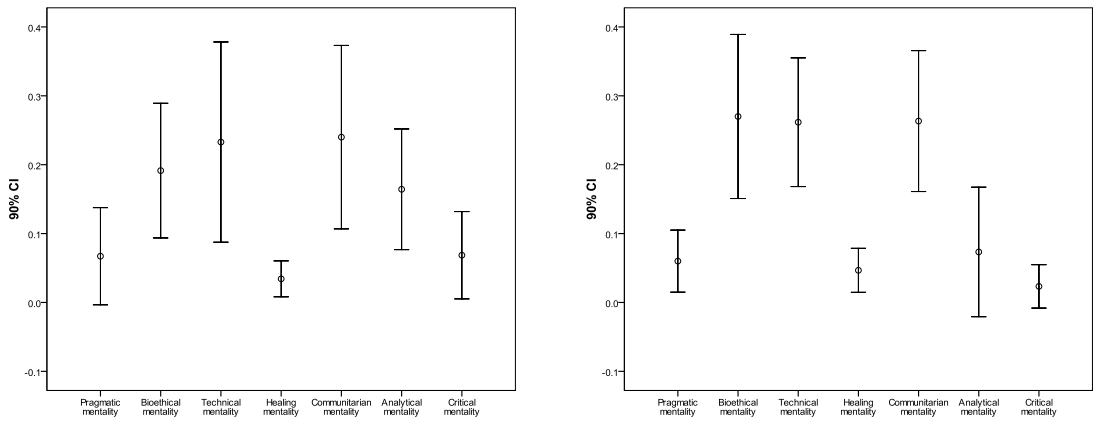


Due to ideological similarities, the *technical mentality* has direct influence upon the *bioethical* and *healing mentalities,* which rapidly accept the political discourse pouring from it. The same phenomenon occurs at the communicative side, but here the political relation between the *analytical* and *communitarian mentalities* is curtailed by the ideological interference of the *technical mentality,* which ends up having more political say within the communitarian realm.

In Chapter 4, it was said that my interviewees favoured bioethical and communitarian claims.[85] In this way, one might assume that the phenomenon of *mental colonization* is of minor importance. However, by using the tools of inferential statistics, we can consider my interviewees as a sample representing their whole committees. This exercise is possible for only committees 3 and 6, for which I have representative samples.[86] Thus, it is possible to estimate what the average score of each mentality would actually be if I had interviewed all the committee members. The following graphics derive from this exercise.

Figure 5.11 – Committees 3 and 6:
Estimating the average score of each mentality for the whole committee

Committee 3 (São Paulo)	Committee 6 (Cape Town)



[85] See section 4.2.8, as well as Figure 4.2 (page 110).
[86] In committee 3 I interviewed 9 members, 5 of which (55%) were either physicians or bioscientists; whereas in committee 6 I interviewed 6 members, 5 of which (84%) were either physicians or bioscientists. These proportions are close to the actual composition of these committees.

With these graphics, I am estimating the average score that would have been obtained if I had interviewed all the committee members rather than only a sample of members.[87] As we are dealing with estimations, we end up having a range instead of precise values. As the number of interviewees is small (9 people in committee 3 and 6 people in committee 6), the estimations of some mentalities have big variations. For committee 3, the actual average score of technical mentality lies somewhere between 0.08 and 0.37. For committee 6, this average lies somewhere between 0.16 and 0.35.

These big variations disturb the analysis but the two graphics are quite similar,[88] enabling us to indicate three trends. First, there is a group of mentalities (pragmatic, healing and critical) displaying small proportions. Second, the *analytical mentality* seems to occupy an intermediate position (almost reaching the top group in committee 3). Third, there is a group of mentalities (bioethical, technical and communitarian) that occupy the top of the ranking.

When we consider the claims actually voiced in my interviews (Figure 4.2, page 110), the technical mentality occupies an intermediate position. Nevertheless, by estimating what happens to the whole committee (graphics above), this mentality assumes an outstanding role. There are good reasons to trust this estimation. In most ethics committees, more than 50% of members are physicians and bioscientists, who tend to favour technical claims.[89] However, among my interviewees (considering strong interviews), only 13 people (38%) have this background, whereas 21 people (62%) have other backgrounds. Therefore, we can suppose that in Figure 4.2, the importance of the technical mentality is under-represented, while the previous estimations correct this distortion.[90]

In conclusion: the technical mentality seems to play an overwhelming political role, be it because of its historical and institutional weight or because of the (direct and indirect) political influences it manages to realize. As a consequence, ethics committees tend to become a fertile field for a specific political discourse to be

[87] The confidence interval is of 90%.
[88] Comparing one same mentality in the two graphics, and looking at the extreme values, we have almost the same numbers for the *pragmatic*, *healing* and *communitarian mentalities.*
[89] See Table 5.1 and Figure 5.13, in this chapter.
[90] Arguably, the massive presence of physicians and bioscientists in the composition of committee 6 explains the low estimations of the analytical and critical mentalities for this committee.

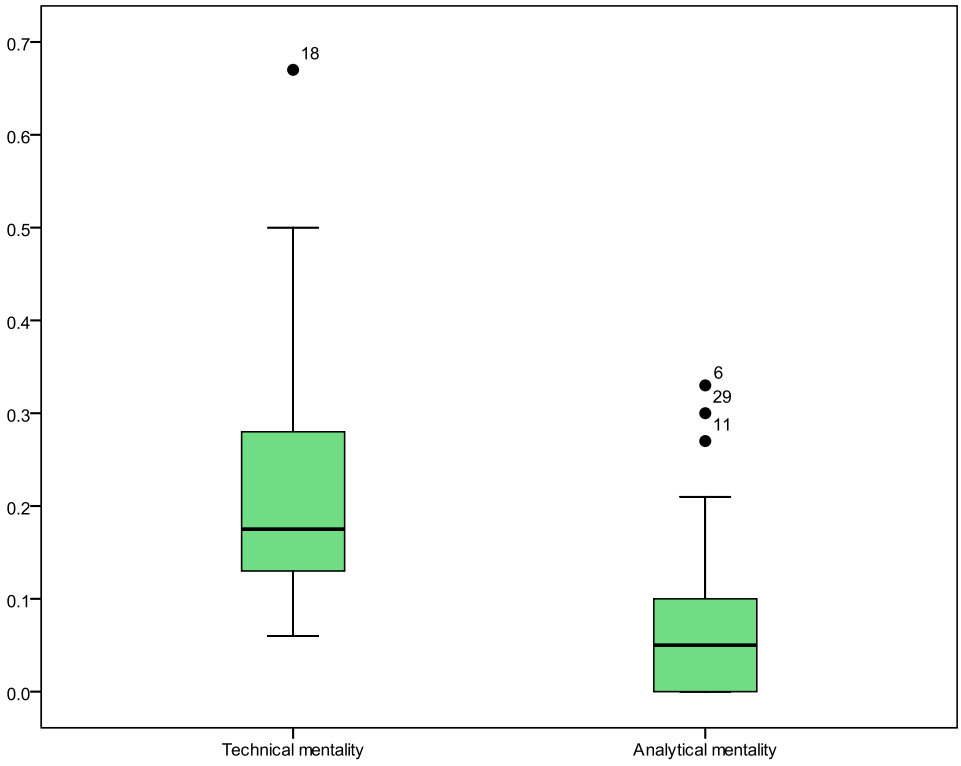
ideologically cultivated, speaking of standards, science, statistics, globalization and studies sponsored by companies.

The following section presents the ways in which the technical and analytical approaches frame the role of ethics committees.

5.3.7 Technical or analytical committees

Of 42 interviewees, only four talked about ethics committees by using ideas that are somehow related to the analytical mentality. In contrast, twenty people conveyed a technical approach to committees. This huge difference can be explained by different phenomena. Firstly, let us consider the following *discourse boxplots.*

Figure 5.12 – Discourse bloxplots: technical and analytical mentalities



The proportion of analytical claims remained clearly below that of technical claims. The median of the technical and analytical mentalities are of 0.17 and 0.05,

respectively. By performing a statistical test,[91] a very strong significant difference was identified.[92]

Thus, the technical approach seems to be much more consolidated in the ethics committees I studied, a phenomenon that can be explained in two ways. Firstly, as seen in Chapter 4, the *bioethical mentality* provides committee members with a strong practical reference. As this approach can be smoothly associated with the technical approach, the bioethical/technical mindset acquires more and more space. Secondly, the technical (contrary to the analytical) mentality has been highly institutionalized. Universities, scientific associations, academic journals, and sometimes even the media, speak the technical mentality's language. The analytical mentality, with its recent development and its low level of institutionalization, can barely balance this technical weight. Thus, every type of issue tends to be addressed from a technical rather than analytical point of view, and this is also valid for the issue of ethics committees.

Technical views of ethics committees are frequent also because as claimed in the previous section, members who embrace the communitarian mentality tend to use technical claims to speak of committees. In other words, the phenomena of *mental inversion* and *mental colonization* help to disperse a technical approach to ethics committees.

How can we then define this technical approach to ethics committees? The main idea is that committees do not review research proposals from the outside, for they are actually part of the clinical research system. Thus, the scientific progress sought by researchers is complemented by the reviewing tasks of committee members.

> "The industry does not wish to just do research and develop products. The industry wishes to have a final product that is viable. They don't need a compound that will need a recall after one year and will be withdrawn from the market. That is why they are concerned with their quality standards [...] They establish relations to research centres by making sure that taps are in the correct place or fridges work in the right temperature. Equally, the issue of ethics belongs nowadays to quality standards, and that is also true for the industry [...] Sometimes they [companies] criticize us

[91] Wilcoxon test (2 related samples) for non-normally distributed data.
[92] p less than 0.0005.

[committees] because of our deadlines [...] Have we got problems in terms of deadlines? Yes, we have. We can improve, incorporate technologies and solve these problems. But we've got quality [...]."
(São Paulo/C4/Bioethicist/05-11)

"You have basic research, you have clinical research, and you have the side of bioethical and social aspects pertaining to all this research [...] I often say that without the bioethical side playing its role, you cannot circulate among the others, because you cannot develop, you don't begin with a standard that is accepted as being... that is acceptable, ethically speaking. So you don't do the so-called good science. Good science follows a range of prerequisites and standards of behaviour that... It is as though you put a stamp saying that you're doing good science, you know."
(São Paulo/C1/Bioethicist/02-11)

From this point of view, committees are not alien to a scientific universe that is composed by standards, scientific methods and certified procedures ("stamps"). Eventually, committees, and especially those which are based in universities, come to be seen as a sort of academic department.

"*The committee members don't get paid for this work.*
Yes.
Do you think they should get paid?
[Immediate reply.] No, I don't see any ethical compelling argument in favour [....] I think this is just part of the duty of being... part of the duties that come with being an academic. So scientists and academics are pursuing knowledge, right? And I think in the pursuit of knowledge, there is a duty to make sure that the pursuit itself is of an ethical nature."
(Cape Town/C7/Bioethicist/08-11)

"I think the committee does follow a scientific protocol. Because projects arrive and there are guidelines, according to... Actually, I don't know where these rules come from, but I think they also have a scientific nature. Because there are phases to comply with, when we're doing the reviews. I think that it has a scientific nature, you know."
(São Paulo/C2/Nurse/04-11)

Thus the ethical guidelines followed by committees would be a sort of extension of the scientific guidelines followed by clinical researchers. The argument goes on that committees, once they are integrated into an academic scenario, must play all the roles played within universities. Therefore, they would also be supposed to accomplish teaching tasks.

> "*[...] And generally, do studies have a good scientific underpinning?*
> [...] what we get from the pharmaceutical industry is generally well-organized and well-described; generally, but not always. In the other part that we analyze, which is the part of student projects, there are many methodological flaws, and we're even willing to teach the person who is submitting the new protocol. So we explain where we think the flaw is [...]."
> (Porto Alegre/C5/Physician/05-11)

> "*And in your opinion, what is the main goal of an ethics committee?*
> To see to it that trials are done ethically and safe and [pause] to... Sometimes, it could be that people are also ignorant of... (the people that put the protocol together) it could be that they are ignorant of certain things, and then the ethical committee can review the trial and then give advice. Because sometimes it is people that are new to research, you know, and then the people on the committee, when they review it, they can see: 'Here there are loopholes, here there are things that should be corrected...' and they can give that advice [...]."
> (Cape Town/C6/Nurse/08-11)

In the end, committee members would be conducting a sort of anonymous academic job and would therefore be comparable to peer-reviewers contributing to academic journals.

> "*Do being a researcher and being an ethics committee member cause any kind of... duplicity? [Laughter.]*
> No.
> *Of double personality? Because, sometimes, it seems that these two roles don't match.*

> No, they match, because you're assessing something that is your own activity [...] Look, there is something that exists in any field of knowledge: peer review [pause]. So the peer review [laughter] is the best way known to mediate something. This is true for any field of knowledge, any field of human relation, of scientific relation. Peer review is a fundamental point, not only in Brazil, we're talking about the world. I mean [laughter], the assessment by peers is the essential point. And why? Back to what I said. I mean, there is no better assessment than the one which is made by someone with adequate knowledge in the field, which includes ethics."
> (São Paulo/C3/Physician/04-11)

Here, there is, once more, much leeway for the mental colonization suffered by holders of the communitarian mentality. According to the technical approach, committee members are undertaking a useful scientific work while remaining anonymous and hidden. This idea attracts holders of the communitarian mentality, who appreciate good deeds undertaken behind the scenes, without widespread recognition. Formulating a technical/communitarian claim, some committee members end up framing their actions as scientific/social service or contribution.

> "Look, our ethics committee, like committees in most places, doesn't offer remuneration, doesn't offer any kind of benefit [...] So why am I saying that? Participating in an ethics committee isn't exciting at all [laughter]. Is there any advantage? No. You have to study things that are not in your expertise area, you have to become familiar with issues that sometimes aren't directed related to your work, so it is... I think it is a contributing role. I like teaching, I've been a lecturer for many years, I think this is part of a sort of general contribution to knowledge [...]."
> (São Paulo/C2/Physician/04-11)

These technical claims, which foreground the scientific worth of committees, can be easily coupled with bioethical ones, and the final result is the idea that ethics committees are supposed to take care of both ethical principles and scientific standards.

When it comes to ethics committees, the analytical mentality has, once again, a cautious attitude. Considering that clinical research, and especially studies sponsored

by companies, are fraught with interests, committee members would have to carefully analyze proposals in order to distinguish between relevant and irrelevant projects.

> "*What would be the main goal of an ethics committee?*
> [...] In my opinion? Well, in addition to its legal functions [...], I think an ethics committee does precisely this selection, you know, this scientific selection of research with human beings, you know [...]
> *Hm. So it selects.*
> Yeah, it is a selection.
> *It distinguishes between research that is... how can I say that... research that is interesting and the one that is not so...*
> Of course. To identify the research that is relevant, always searching for human dignity, as legal people like to put it [...]."
> (Porto Alegre/C5/Lawyer/05-11)

In this example, even though I did not invite the interviewee to further explore his claim, the idea of selection appears as a novelty, being strange to the realm of the technical mentality. Admitting that some studies come to be more "relevant" than others differs from the technical view, according to which all studies can be commensurated at the outset, because they all look for knowledge advancement. Another interviewee voiced a claim expressing an analytical approach to committees:

> "*In your opinion, what is the main goal of clinical research?*
> [Deep breath.] Now, clinical research... Are you talking about academic research?
> *No, I'm talking about both, academic and industrial...*
> Oh, then, you've got to split it quite clearly. I've no doubt, in my mind, that the drug companies design their trials in an attempt to show that their drug is better than the existing drugs. I think clinical research is much clearer, there is no financial incentive... There are some incentives. I mean, if you get a PhD, you're more likely to become a professor, you're more likely to go overseas and things like that. But it is my impression that their research is more directed at trying to advance our knowledge. And I think you've got to split this very carefully between the two."
> (Cape Town/C6/Physician/08-11)

Thus, in the analytical mentality, it is impossible to talk about research in a general way. It is rather necessary to "split it," putting academic studies on the one side, industrial trials on the other. Moreover, the real search for knowledge would be implemented not by companies but by independent researchers. In this way, the analytical mentality *converses* with the *background knowledge*, a normal attitude to it.

This same interviewee gave me an example (a typical analytical attitude) of clinical trials in which he has not been involved either as investigator or reviewer. According to what he said, some pharma companies have tried to explore a class of drugs called biological agents. Even though some studies have shown that it would be more efficient and less expensive to combine old compounds, therefore safeguarding national budgets, these actors are carrying on with their studies, sometimes applying available drugs in very low dosages in order to show clinical improvements.

> "[...] So you see, this is why I think one has to look at the whole picture, and this is why I think the facts that I've mentioned to you are becoming important, because it is the ethics committee that actually should be trying to... [pause] regulate this sort of thing. And I think this is an example of a gross expenditure which the world doesn't need [...]."

Thus the analytical mentality assumes that ethics committees need to stop working with general concepts and begin to delve more accurately into methodological aspects, in order to select proposals that are socially relevant. In this effort, companies should be looked at more carefully, because of their interests and willingness to reach financial targets by any means. From the idea of committee-facilitator, which prevails in the technical mentality, we go towards the idea of committee-inspector.

> "*And in your opinion, what is the main goal of an ethics committee?*
> It is to control. You have to... You can't just leave people go ahead and experiment with people. That's what they're doing. A trial is an experiment. When you look at some of the things that they want people to do, it is like: 'My God! I wouldn't do that.' Oncology trials, to me, are the worst. You take a person who's got three months to live

and want to give him a new drug. No way! I don't agree with that at all [...] No, we need an ethics committee, otherwise the industry would run... you'd have trial all over, people would be advertising: 'Join... Come to our trials, blah blah blah, we're trying a new drug, do this, do this.'

So the committee has to control the industry.

Definitely. Definitely.

And that is a hard job [laughter].

It is a hard job [laughter] [...]."

(Cape Town/C7/Lay member/05-11)

"It is hard, I think, to be places like South Africa and Brazil, because of that actual job. Because there are people who want to put funding in there and it is tempting for the researchers to get the funds, but, you know, you have to control those ones at the top [laughter].

Yeah. And that is hard to do.

You have to put limits on them, yeah. Because they've got all the power [laughter] [...] They're second only to the armaments industry. Hm, it is big money!

Yeah.

And they play with poverty. Sickening! [laughter]"

(Cape Town/C7/Social scientist/07-11)

These claims are still highly shaped by communitarian concerns, such as physical sufferings and international inequalities. However, it seems that the *analytical mentality* will not be able to diffuse its political view without allying itself to the *communitarian mentality.* As soon as more committee members are willing to describe pharma companies as research tricksters, rather than research gurus, an analytical view to committees will certainly have more leeway to be diffused. In the political scenario of ethics committees, the *communitarian mentality* has become a strategic battlefield, on which the *technical* and *analytical mentalities* struggle to impose their views.

5.3.8 Political implications of the technical and analytical mentalities

The following *discourse boxplots* show the proportions of technical and analytical claims according to professional background.

Figure 5.13 – Analytical mentality (South Africa and Brazil): discourse boxplots according to background

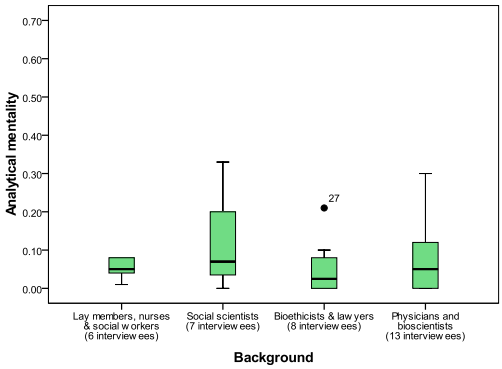
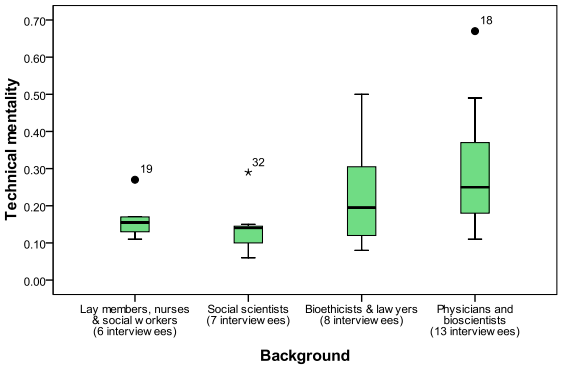


Figure 5.14 – Technical mentality (South Africa and Brazil): discourse boxplots according to background



We shall scrutinize these graphics in three stages. Firstly, we see the boxplots going up as we shift from the analytical to the technical mentality, with the exception of social scientists (who display a decrease). By performing a statistical test,[93] I found significant expansion for lay members, nurses & social workers (p=0.03), bioethicists and lawyers (p=0.03), and physicians and bioscientists (p=0.00). This outcome corroborates what has been said throughout this chapter: bioscientists and physicians, when choosing between technical and analytical claims, tend to favour the former. The expansion in the first group (lay members, nurses and social workers) is a graphic and statistical demonstration of the phenomenon of *mental colonization.* In fact, these committee members tend to adopt communitarian concerns, being thus subjected to the ideological influence of technical claims.

Secondly, focusing on the analytical approach (Figure 5.13), no clear difference can be seen. Thirdly, we can compare boxplots within the technical approach (Figure

[93] Wilcoxon test (2 related samples). Exact values quoted.

5.14). We see that bioethicists, lawyers, physicians and bioscientists voiced higher levels of technical claims than interviewees with other backgrounds.

These nuances do not remain within the universe of committees but can also be verified in several social spheres. Over the last years, some authors have published papers and books in which they denounce and unravel, in an analytical vein, the subtle manipulations carried out by pharma companies in clinical trials. As we have seen, the analytical language operates with the tools proposed by the technical mentality but tries to derive unexpected conclusions and meanings. Thus, it is not surprising that:

> "The first critique comes from clinical researchers and statisticians themselves [...] Such critique proceeds by elaborating on the methodological difficulties of doing trials, and on ways to mitigate their effects using new techniques for data review and summation" (Will and Moreira, 2010, p. 2).

This analytical stance may have practical manifestations. In the United States, for instance, Aids activists who "invaded" clinical trials in the 1980s to provide their personal feedback, ended up being recognized by national regulatory agencies (Epstein, 1996). Even though this recognition came to eventually appease their political energy, they proved that scientific domains can also be subjected to non-expert scrutiny and guidance. Nowadays, non-experts continue to be important for the design of clinical protocols, giving their input in topics as diverse as priority areas, ethical aspects or informed consent procedures (Oliver and Buchanan, 1997, Thornton, 1998, Hanley et al., 2001, Koops and Lindley, 2002, Caron-Flinterman et al., 2005). As Faulkner (2010, p. 138) showed, clinical trials are likely to generate social debates, for there are situations when "[...] the scientific space becomes more socially permeable." In a sense, as Rothman (1991) argued, the ethics committee model itself can be considered as an intervention by non-physicians in the domains of experimental medicine.

To be sure, holders of the technical mentality will react to such non-scientific intrusions. In Brazil, for instance, the national government launched, in the 1990s, a research program to study a drug produced by the American company Cerezyme. The medicine, aimed to treat the Gaucher's disease, is provided for free by the Brazilian government. With the program, frailties of the original trial could be unravelled and

new effective dosages could eventually be discovered, leading to savings in the Brazilian Ministry of Health's budget. The program was immediately condemned by many Brazilian scientists, who argued that political and ideological concerns were distorting the scientific assessments done by the medicine's producer (Petryna, 2009). Thus, it is clear that technical claims can be used to speak not only of particular research projects but also to gauge a national policy's worth.

Actually, the technical mentality has been able to acquire an overwhelming power thanks to a twofold movement. Firstly, some technical claims have been largely diffused, reinforcing the phenomenon of *mental colonization.* When it comes to affirming its ideological influence, the technical mentality proves particularly greedy, spreading its claims through several social relations. For example, Jill Fisher verified that in clinical trials, study coordinators frequently give informal lectures to participants, explaining the meaning of participation and research. "[...] coordinators are trying to show subjects that they are part of something bigger than themselves: the advancement of scientific knowledge and the progress of medicine" (Fisher, 2009, p. 174). By means of such pedagogic efforts, everyone is invited to join the ideological universe of technical mentality.

Secondly, and complementing this ideological diffusions, it has been possible to maintain domains to which scientists have privileged or exclusive access. For example, in ethics committees, bioscientists and physicians continue to be the members who receive the biggest proportion of drug studies to access, whereas members with other backgrounds deal with the plethora of academic ("low-risk") studies with which committees overflow. In the committees I studied, reviewers are selected by the committee chair with help from some secretaries,[94] and the main criterion used in this selection is the members' expertise area. In Cape Town, this issue emerged in an interview with a committee chair:

> "*And all the members are reviewers.*
>
> Er... Yes, all the members are reviewers but, obviously, we won't let the person that is representing the community review a difficult trial. You know, they would provide inputs into the trial but they won't be a primary reviewer of the project.

[94] The exception is committee 5, in which the distribution of projects is exclusively undertaken by the committee's secretary.

Ah, okay. So for clinical trials, the primary reviewer is always a physician.
Er... depending on the nature of the trial. So it will be a physician or somebody in the sub-specialty or something like that, yeah. Yeah."
(Cape Town/C6/Physician/08-11)

Nowadays, some drug studies include certain qualitative tools, a circumstance that renders social scientists more likely to review them as well. For the most part, however, bioscientists and physicians continue to be favoured. In one committee I studied in Cape Town, for instance, the chair tries to always include a pharmacologist into the review of drug studies. In this way, most members remain isolated from the world of trials sponsored by pharma companies. The point to be made is that without having such reviewing experience, committee members who embrace the *communitarian mentality* are less likely to "take the ideological stairs" leading up to the *analytical mentality.* This is so because for reviewers with no bioscientific or medical background, the only way to become capable to assess the methodological side of drug trials is to actually read proposals, struggle with them, identify relevant scientific issues, and formulate personal strategies to cope with all this complexity.

One of my interviewees, a social scientist, voiced a *discourse* that was strongly marked by analytical concerns.[95] She says that when she began to receive protocols pertaining to drug trials, the task proved very difficult.

[...] I made this point, you know, in the sense that: 'Look, I'm not the most competent person to do these reviews. You could get other people' [...] When I said: 'Look, it gives me much work, I read the project over and over again...' I got this answer: 'Look, this is a positive issue.' Because those who work in the area think they understand, they read it and skip pages in the reading. And as I don't work in the area, I have to understand, based on the project... Either the project is very well-written or I cannot understand it, you know. And to me, personally, this has to do with both the quality of the project and myself, because I have to go back and forth to understand what is going on [...]."
(São Paulo/C3/Social scientist/05-11)

[95] The *discourse graphic* is presented on Chapter 6, Figure 6.3.

She has been involved with ethics committees for ten years. In addition to the committee I studied, she is member of another committee in São Paulo. As a result, she has become "a sort of specialist in the design of research protocols," according to her words. She developed her own techniques to review projects, involving frequent consultations to medical online databases such as Medline.

> "So what I see is that there are phases. My reviews have not always been like that. So I think this is maturity. We get mature, you know. My experience [...] showed me that this is very serious, that we can't... I'm not talking about meetings. But you can imagine the number of reviews in clinical research I've done [...] It is much work, you know. And then, you learn, you build it up. So I think it is a process, you know. So, today, I wouldn't review a clinical trial without having access to the internet, without having at least a primary and general look on that... At least on Medline."

Therefore, even committee members who lack a medical background can acquire satisfactory skills at reviewing protocols, because reviewing projects demands abilities different from those which are necessary to design or conduct clinical studies. However, for most members, these abilities are kept at bay, for two reasons. Firstly, there is the simple fact that most members are not assigned the review of drug studies and cannot become familiar with this task. Secondly, as committee members work on a voluntary basis, some members simply leave the committee after some years, thus abandoning the experience they have acquired. Shifts in the committees' composition are more frequent in Brazil than South Africa; most Brazilian committees establish a four-year term for their members.

Thus, for most members, and especially newcomers, the theoretical framework provided by science (as well as the ideological framework provided by the bioethical mentality) becomes a sort of scapegoat, which is much more easily accessible than the notions of the analytical approach. As a consequence, there is only a small number of members who eventually take the lift from the *communitarian* up to the *analytical mentality.* The non-professional nature of committees, coupled with the (technical) idea that drug trials should be reviewed only by specialists, help to maintain the ideological primacy of bioethical and technical claims within ethics committees.

Arguably, this phenomenon takes place not only in committees but in other bodies dealing with clinical trials, such as regulatory agencies. For example, Jasanoff (1990, p. 229), studying the US Environmental Protection Agency (EPA) and Food and Drugs Admistration (FDA), concluded: "Regulatory practices at EPA and FDA would seem to indicate that the technocratic vision of public policy has scored important gains over the competing democratic paradigm." So far social science studies have been conducted to verify regulatory agencies' financial or institutional conflicts of interest, speaking of "regulatory capture" (Huntington, 1952, Bernstein, 1955, Stigler, 1971, Kalt and Zupan, 1990, Levine and Forrence, 1990, Laffont and Tirole, 1991). One could also argue that in some occasions, these agencies can suffer from "ideological capture," for they may end up suffering the *mental colonization* imposed by technical views springing from pharma companies and CROs.

Potentially, the technical approach can become appealing for several social groups. During my fieldwork, for example, there was a debate going on in Brazil about the review of the Resolution 196, which established, in 1996, the first Brazilian guidelines on clinical research and ethics committees. Since that moment, more than 600 ethics committees have emerged, most of which are not really qualified and well-equipped for their tasks. In the National Council of Health, but also in the National Commission for Research Ethics and some departments of the Ministry of Health, a (*analytical*) feeling was gaining momentum, during my fieldwork, stressing that Brazil needed stronger and more qualified committees. As a result, the National Council of Health drafted a new Resolution, which was published on the internet so that different groups could assess it and give their feedback.

Once the draft legislation was published, many people, including members of the Brazilian Society of Bioethics, voiced concerns with international guidelines, which according to their view, should be complied with and accurately quoted in the new legislation. The Brazilian Society for Pharmaceutical Medicine (SBMF, *Sociedade Brasileira de Medicina Farmacêutica*), an association gathering physician-researchers, reacted by publishing an alternative draft, which had very disciplinary features, including many scientific definitions and details of procedures to be looked at in the conduct of clinical studies. Another actor was the Brazilian Society of Clinical Research Professionals (SBPPC, *Sociedade Brasileira de Professionais em Pesquisa Clínica*), which is organized as an independent, non-profit organization. This Society had been

engaged in partnerships with small local companies that offer training courses on clinical trials, on the one hand, and maintained indirect relations to multinational pharma companies and CROs, on the other. When the proposal of the new legislation was published, SBPPC begun to campaign for the process to be interrupted because according to this Society's view, time should be allowed for more debate. At the same time, it organized some discussion meetings, which were open to the public and aimed to facilitate the reflection that according to SBPPC, was necessary.

Then, the renewal of the Brazilian regulatory framework, motivated by *analytical* concerns that emerged mainly in the Ministry of Health, awaked many types of claims. The *bioethical mentality* manifested itself in the concerns with international guidelines. The draft prepared by SBMF expressed *technical* concerns with scientific standards. Finally, the SBPPC's campaign seemed to be an attempt to foster *mental colonizations* by means of a public mobilization that could underpin the Society's effort to turn the Brazilian clinical research scenario into a professional, standardized and globalized environment. At the same time, of course, pharma companies and CROs were knocking on the Ministry of Health's doors, feeling that the time had come to finally try to speed up the slow turnaround times of the Brazilian ethical review system.

In the framework of my study, I focus on the existence and relationships of *rationalities* and *mentalities* within ethics committees. Nevertheless, as soon as one tries to look at broader scenarios, it is possible to surprise the same *rationalities* and *mentalities* being constantly marshalled in order to built up political discourses. Political processes involve not only resources, funds, weapons and other sorts of material products; they also have to do with *discourses, claims,* ideologies and *rationalities*. Therefore, the comprehension of the ways in which *mentalities* are formulated and combined, not only in particular institutions but in society at large, is paramount for political studies.

5.4 CONCLUSION

By studying and comparing the *technical* and *analytical mentalities*, we cannot verify the complementarities identified in the comparison between the *bioethical* and

communitarian mentalities. On the one hand, technical and analytical claims do not maintain a frequent *conversation*, sharing only concerns with the methodologies advanced in clinical studies. On the other hand, the technical approach has been more ideologically effective, in the sense that committee members tend to favour technical rather than analytical claims when dealing with issues of clinical research and ethics committees.

The technical mentality's ideological success has to do with the following circumstances.

- We are dealing with a secular philosophical construct whose consolidation and expansion is guaranteed by a vast set of institutions such as universities, scientific associations, academic journals, the media, among others
- The scientific expertise of bioscientists and physicians is largely recognized and respected by committee members
- Scientific concepts and statistical tools can provide committee members with concrete yardsticks to assess research projects
- The ideas of improvement and progress, which are central in the *technical discourse*, sound quite meaningful and appealing to members of different backgrounds

On the other hand, the precarious diffusion of the analytical mentality can be explained by another set of reasons.

- The relatively recent emergence of this approach has not yet allowed enough time for a solid ideological development. In a sense, analysts are not simply holding a mentality but also building it up
- In order to be embraced, the analytical mentality requires either some scientific knowledge or much experience at reviewing drug proposals. Both characteristics are not very common for many committee members, who can stay in the committee for only a couple of years or can be kept away from the analysis of drug protocols

- The analytical approach often counters the technical approach; the ideological success of this latter impose barriers to the diffusion of analytical claims
- So far the analytical mentality has not elaborated clear references to guide committee members in their reviews. In this way, for most members, and especially those who are new to the world of clinical research, the analytical *discourse* can sound murky or too politicized

These asymmetries are important because at this level of the *foreground knowledge*, *discourses* have to do not only with moral stances but also with political stances. In other words, both the technical and analytical mentalities are engaged in a discussion about the ways in which clinical trials should be assessed by ethics committees and government agencies. The technical approach stresses the relevance of scientific standards and the accuracy of trials undertaken by pharma companies and CROs. The analytical approach has a much more cautious stance, especially in its assessment of industrial studies. Thus, it proposes to delve into methodological details, trying to detect manipulations or too flexible choices that protocol designers make in order to preserve financial interests.

Once again, it is important to remember that even though these approaches tend to stress methodological aspects of clinical research, their language can always be translated into common terms and be made understandable to most committee members. In the case of technical claims, this translation is quickly done, for society has formulated many artifices to make scientific notions become diffusible and largely recognizable. For instance, the media helps circulate scientific notions kept at superficial levels in order to sound, at the same time, clear and legitimate. As for analytical claims, their translation has been more problematic, for the process seems to depend, to a large extent, on personal attempts to unravel the intricacies of clinical trials.

If these mentalities reflect political discussions, there is a necessary corollary: the stances they represent may at any moment reach extreme degrees. In this way, one can speak of a technical and analytical fundamentalism or, more precisely, a *healing* and *critical mentality*. Studying these extremes views is our goal in the following chapter.

Chapter 6 – Back to background knowledge: the healing and critical mentalities

The mentalities focused on in this chapter are an extension of those studied in Chapter 5. We can say that they take the stances advanced by the technical and analytical approaches to extreme degrees. This is the reason why the chapter begins with a brief overview of the sociological study of extreme behaviours and ideologies. The mentalities we begin to study now (*healing* and *critical mentalities*) do not share characteristics. This is why we shall study them in two separate moments, beginning with the *critical mentality* and then moving on to addressing the *healing mentality.*

6.1 IDEOLOGY AND EXTREME VIEWS

As Lévi-Strauss (1964) classically argued, social life always implies certain efforts of classification and organization. To be sure, some leeway for creative arrangements can always be found but in order for groups to have some stability, a certain degree of normalization is needed. According to Habermas (1996), social life involves both *validity*, defined as the flexibility and freedom for negotiation implied by communicative actions, and *facticity,* which refers to fixed rules and meanings for which negotiation is closed. If as Geertz (1973) argued, culture is a net of meanings knitted by men, there is flexibility in the act through which meaning is established but a great deal of rigidity in the compliance with meanings previously determined.

Thus classifications and normalizations are ubiquitous social events. This ends up imposing more or less serious difficulties to people that are somehow perceived as different, such as those who are mentally ill (Estroff, 1981), physically disabled (Oliver, 2009, Mladenov, 2011), or outlaws (Hobsbawn, 1969/2004). This was perhaps the inspiring evidence for Durkheim (1960) to claim that society imposes normalization to individuals, and therefore the normal person can be defined as the average person.

Nevertheless, Durkheim himself recognized that at certain points, some individuals can propose new ideas and behaviours, which are quickly rejected but may

subsequently acquire more acceptation and eventually guide society toward new pathways. Thus social actors who struggle with established norms can eventually play decisive roles and introduce scientific, philosophical and behavioural changes.

In the previous chapter, it was shown that the *technical* and *analytical mentalities* are involved in a political debate. In some of their claims, these approaches are not only distinct but also mutually exclusive. For instance, the technical approach tends to frame pharma companies as models of clinical researchers, a capacity that is attributed to their financial resources with which all the details of trials can be carefully looked at. The analytical approach is very cautious (and even suspicious) toward pharma companies, assuming that methodological flaws can derive from financial interests. Obviously, these stances can eventually constitute extreme views. In this way, pharma companies would be seen either as fully-fledged scientific masters or scientific charlatans.

Even though such type of attitude proved quite rare in the interviews I conducted, it was possible to identify two divergent kinds of extreme discourses. On the one hand, there is a range of claims that expand some conclusions taken from the *technical mentality*. As a result, some ideas such as universal benefits and therapeutic progress end up being overstated. On the other hand, some committee members take some conclusions selected from the *analytical mentality* to unexpected heights. The final result is a set of claims that depict clinical trials as a domain fraught with insurmountable flaws.

Even though these extreme *discourses* draw heavily on the ideological work carried out by the *technical* and *analytical mentalities,* they do contain some ideological novelties, such as the ideas of *therapy* and *crisis,* which appear as pivotal elements. Eventually, there emerge two ideological trends that can be summarized in the following fashion:

- Clinical research promotes progress and knowledge, which are materialized in medicines and procedures endowed with *healing* capacities

- Clinical research contains methodological and procedural flaws that are necessary to the whole system, and that is why we can speak of a *critical* enterprise

This chapter aims to describe and interpret these two stances, which I call *healing* and *critical mentalities.* Contrary to what happens to other approaches, here ideological *conversation* disappears. In other words, there is neither common claim nor political debate between these two mentalities. They follow different pathways, identifying different relevant issues and applying different schemes. As we can see in Figure 3.1, page 71, these are the only approaches that do not share something with another approach located in the contrary field of *rationality.* The only small trait they do share is the fact that they are extreme views, and this is why they are presented here in this same chapter. However, the differences between them are so salient that my exposition is realized in two moments. Firstly, I shall describe the *critical mentality* and once this task is accomplished, I move on to discussing the *healing mentality.*

6.2 THE CRITICAL MENTALITY

In the history of social and economic thoughts, the idea of crisis has been invoked several times. Two main ways to deal with this idea can be identified. First, there is an interpretative tradition inspired by Schumpeter, according to which capitalism operates by creating and finally overcoming successive crises. Through a process of "creative destruction," capitalism is always unmaking the previous situation, triggering new arrangements and forestalling stagnating processes (Schumpeter, 1942/1954). Second, the tradition of thought initiated by Marx points out that capitalism is a huge crisis itself. Through a productive process which generates decreasing surplus value, capitalism would slowly march towards self-destruction. This second notion of crisis is precisely the one which is embraced by the *critical mentality.*

Here, crisis is not seen as an error to be corrected; rather, it is hailed as an insurmountable trait of clinical trials.

This is the view that comes to be advanced in Adriana Petryna's studies. She claims, for instance, that in clinical trials, adverse events are poorly reported and harms are under-hypothesized. "Such underhypothesizing does not necessarily mean deliberate suppression of adverse events. Rather it reflects logistical incapacities of the trial operational model and of the system of modern drug regulation that created it" (Petryna, 2009, p. 27). Here, the idea of interests, which travelled from the *pragmatic* through the *communitarian* and into the *analytical mentality,* tends to have less importance. In critical claims, research flaws have to do with the organization of the whole research system and appear as necessary elements.

Petryna (2005) proposed the idea of "ethical variability," arguing that ethical standards followed by the trials industry vary according to the country and the social context. In countries marked by intense social and health crises, standards can be relaxed (Petryna, 2005, Petryna, 2009). "But one can also ask, are crises exceptions or are they the norm? To what extent does the language of crisis become instrumental, granting legitimacy to experimentation that otherwise might not have any?" (Petryna, 2006, p. 43). Therefore, Petryna's analyses are a good example of a critical view, for her claims suggest that the state of crisis as an inherent and necessary feature of global trials.

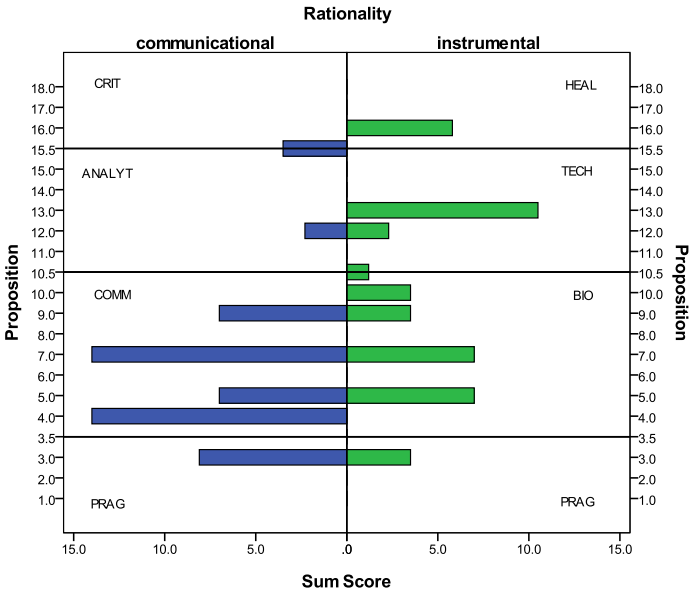
To be sure, this type of analysis is also shaped by concerns that stem from *background knowledge* and are subsequently processed by communitarian and analytical views. However, there is something new in the critical mentality*,* for it is neither shaken by the emotional tones of the communitarian discourse nor paralyzed by the heavy methodological concerns of the analytical discourse. The critical mentality, albeit stimulated by pressing concerns identified by its *communicative* counterparts, leads to sober discourses. Thus, it is important to be able to distinguish between a true critical discourse and a *proto-critique* that is mainly informed by communitarian concerns.

6.2.1 The idea of proto-critique

Throughout my explanation, I used some *discourse graphics* to depict the ideological structure of some *discourses.* As the pragmatic approach belongs to both the *instrumental* and *communicative rationalities,* the bars corresponding to this approach are symmetric. However, there are some cases in which this symmetry is broken, like in the following *discourse graphic.*

Figure 6.1 – Discourse graphic n. 28

(Cape Town/C7/Social scientist/07-11)



Whenever interviewees voiced pragmatic claims, I attributed scores to both the instrumental and communicative sides. However, by looking at the graphic above, we see that pragmatic claims show a higher score at the communicative side. This happened because at certain points of this interview, some claims were voiced which I considered as *proto-critique*. In the following quote, I take one example from this committee member's interview:

"*Over the last years, there has been a great expansion of clinical research. There are more and more protocols, more and more studies... Do you think that this expansion is important and necessary?*

Not always.

Not always. And why?

Well... I think that medicine has become dominated by the pharmaceutical companies and I think that whilst, often, very valuable compounds have been tested for diseases such as cancer, it is not always true that, say, for instance, in this context, those compounds are going to be available to the general population. So the research and testing happen in South Africa but the medications aren't available [...] I'm a lot circumspect about pharmaceutical companies. And they make such vast profits. And I think medicine is about care. And I think a lot of the committee work that we do goes to pharmaceutical companies, to developing new protocols and following through clinically based research rather than actually generating research on the ground here that is maybe more meaningful [...] And a lot of money might be coming in from the pharmaceutical research but [...] tends to go to researchers who are involved with the pharmaceutical company [...]."

(Cape Town/C7/Social scientist/07-11)

In my fieldwork, other interviewees trumpeted similar complaints:

"So, you know, you're interested in clinical trials. I'll give you some good views [laughter] [...] This is just my view and it came through my experience, so consider what I'm saying in that sort of context. [Pause.] I can't escape the feeling that there is a lot of easy-thinking about clinical trials that happen in this country. There is a lot of people who... I have a strong suspicion that there is a bit of, you know, it is cheap, it is easy to do clinical trials in a country like South Africa because, you know, maybe regulations aren't quite strict or they certainly are much cheaper than they would be if these trials were conducted in another part of the world and, you know, this is a needy country, so any money is better than no money. I think that this is also often the view that people hold. And so it is entirely legitimate for medical doctors in this country to conduct maybe seventeen different clinical trials at the same moment, because they actually find clinical care for his patients, or her patients, and because it also, then... you know, there is a bit of funding that they can use to finance capacity development

in medical research and stuff like that. I think, you know, because this country is a needy country and it is a resource-poor country, or relatively resource-poor, that it is okay to them to do these clinical trials here on the scale that it happens [...]."
(Cape Town/C7/Bioethicist/08-11)

"*Do you think that the fact that there are foreign companies doing research in Brazil is bad?*
Look, it is not, as long as they have partners in Brazil, right? If they're alone, why are they alone? They have to justify it, and they have to justify it *very well*. Are they coming here because there are indigenous populations, poor populations here, and they don't have it there? So let's analyze it [...] But to do it as they did in Africa, in the period of Aids, this is completely non sense, and I don't agree with it."
(São Paulo/C3/Lay member/05-11)

At first sight, it seems fair and correct to consider such discourses as critical. Nevertheless, if we take into account the arguments that are mobilized, it is easy to see that we are dealing with the same concerns that define other mentalities. In fact, there are pragmatic claims (economic interests held by companies and researchers) and communitarian claims (international inequalities, exploitation of vulnerable populations). Thus, instead of a new approach, these discourses express pragmatic and communitarian approaches. Considering the immediacy and the emotive vein with which claims are often voiced in the *pragmatic* and *communitarian mentalities,* there is no surprise in the fact that these *proto-critiques* also assume emphatic tones.

It is the presence of proto-critique that explains the "pragmatic distortion" in the graphic above.[96] Apparently critical and innovative, this stance is actually repeating what has been built up by other mentalities. By the way, proto-critiques can be constructed not only with ideas from *communicational* but also from *instrumental mentalities.* From the *technical mentality* derives a proto-critique according to which companies are failing to comply with established scientific standards, an interpretation that was proposed, for example, by Abrahan (1993, 2007). There is also a fairly widespread proto-critique whose source lies in the bioethical approach, as the next quote exemplifies.

[96] Another example can be seen in Figure 4.3, page 126.

"*In your opinion, what is the main goal of an ethics committee?*

A research ethics committee. It would be, I guess... Again, I'm back, to looking at, I suppose, the quality of the informed consent. I'm not a great believer in the way we push informed consent, that it has to be written in a certain way. I think, I believe that we should be pushing a process of informed consent, of how we get it from our participants [...]."

(Cape Town/C7/Bioethicist/07-11)

In the literature on clinical trials, criticizing the informed consent process and proposing new and more comprehensive processes has become a very frequent (*bioethical*) proto-critique. This notion is in tune with the bioethical conception according to which ethics is a field in constant evolution.

In the case of the *communitarian mentality*, proto-critique seems to be associated with a lack of *analytical* resources, as the following quote suggests.

"*[...] Over the last years, there has been a big expansion of clinical trials in countries like South Africa and Brazil. Do you think that this growing number of protocols is really important and necessary?*

Ah... I don't... I don't know enough to have the kind of... You're talking about clinical trials and particularly pharmaceutical trials. I don't... Personally, what I've read about is things, for example, like me-too drugs, you know. And I think there is probably some significant part of trial work that is driven by companies needing to just produce more patentable, you know, reinventions of previous drugs, which I don't think it is a good thing. I think some of the growth in places like South Africa, Brazil or other places is that drug companies are finding it harder to do work in Europe and the US, because of the regulatory systems there [...] But I don't know the sense of... [Pause.] Yeah, I don't know enough to make my own independent judgment but I imagine that there is kind of good reasons and bad reasons for this expansion."

(Cape Town/C7/Social scientist/08-11)

In spite of being emphatic, proto-critical claims are usually accompanied by qualifications, for as this interviewee points out, information is lacking in order for

definitive conclusions to be advanced. Without being processed by the *analytical mentality*, communitarian claims cannot assume a true critical nature, missing the point where proto-critique becomes actual critique. In addition, these types of proto-critical claims still admit the search for solutions. In a true critical discourse, as we begin to see in the next section, the interpretation assumes a more drastic vein.

6.2.2 Unnecessary trials

One of my interviewees told me that she once found a methodological flaw in a project designed by a pharma company. She pointed to the problem and the principal investigator refused her arguments. A meeting was then organized, involving this reviewer, the committee chair and the physician-investigator.

> "And then I looked at her [the investigator] and said: 'You know, this medicine has counter-indications... it has bigger carcinogenic potential than what is available in the market.' She said: 'Absolutely not. This is not true at all.' And I had downloaded a publication that had appeared one month and a half before the meeting [...] a study that showed exactly that. So I presented her this article, which I had fully printed, and said: 'Look, madam, we have this information here.' And she almost felt on her back. She said: 'Well, I'll look at it, I'll talk to the sponsor to see what the proper procedures are' [...]
>
> *And do you often find this kind of problem? Is that frequent?*
>
> Well, there are problems that are a bit unbelievable [...] this surprises me, you know, and makes me a little frustrated, because it is an easy thing to detect (even I, who don't work on that area, can detect it), I ask for changes, and then, when you point to it, they say: 'Oh, it is true, we should have included it.'
>
> (São Paulo/C3/Social scientist/05-11)

Based on her ten-year experience in committees, this interviewee says that pharma companies may try to push inaccurate research methods, being supported by investigators. In this way, the relaxation of scientific and clinical rules would be an inherent aspect of trials. Juni and collaborators, by studying the Vioxx scandal and

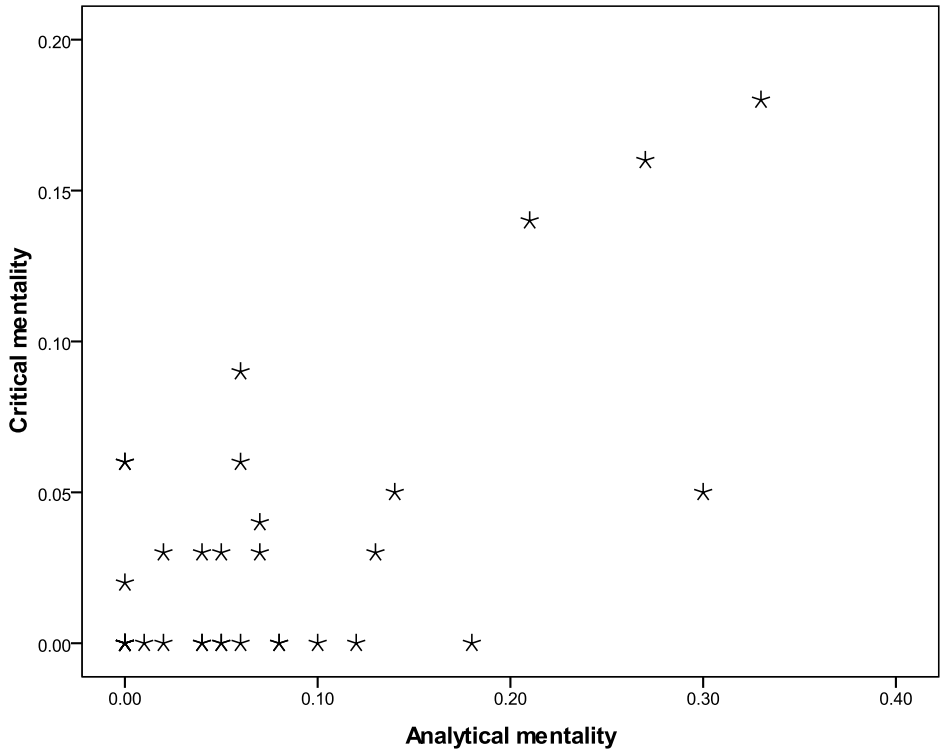
carefully analyzing the data from this clinical trial, argued that Merck was intentionally late in withdrawing the defective and dangerous medicine from the market. If Merck stated, in 2004, that the drug should not remain on the market, "[…] then the same statement could and should have been made several years earlier, when the data [...] first became available" (Juni et al., 2004, p. 2027).

In the *critical mentality*, methodological flaws are framed as a fundamental and necessary characteristic of global trials. In many occasions, this phenomenon is attributed to the commercial nature of pharma companies and CROs, which are always engaged in business competitions and need to design several trials, collect samples and analyze data very quickly.

> "*Do you think there are fundamental differences between an academic study and a trial sponsored by the industry?*
> Yes, I do [laughter]. I think a trial sponsored by industry is profit-driven. Very much so [...] Okay, some academics probably would finally end up in the industry [laughter], okay, but I think while they're still academics, I think they would see to it... they would probably see that the science is [pause] perfect for the trial, whereas I'm not so sure that the industry... I think the industry has so many trials that they want... that they have going at a certain time, and for them it is to get it out, to do the trials quickly to have the results so that they can put the drug on the market. And so that is why I think there is a difference between academically sort of funded trials and then the industry-funded trials.
> *So the industry's trials are more likely to have scientific problems.*
> Scientific?
> *Problems.*
> I would think so. [Pause.] I think so."
> (Cape Town/C6/Nurse/08-11)

Methodological flaws, which are pointed out by the *analytical mentality*, are considered, in the *critical mentality,* as a fundamental aspect of clinical trials. Thus the adoption of the analytical approach is a prerequisite for a full access to the critical approach. The next graphic shows the correlation between analytical and critical claims.

Figure 6.2 – Correlation between analytical and critical claims



There seems to be a positive correlation between the two scores. To test this correlation, I divided the interviewees into three groups according to the following levels of critical claims:[97]

- Low level: null score
- Medium: from 0.01 to 0.06
- High: 0.07 or more

By performing a statistical test[98], I found a positive correlation coefficient of 0.38, which according to Cohen (1988), indicates a medium correlation.[99] Thus,

[97] As critical claims are very rare, these levels differ from those I used for the *pragmatic mentality* in Chapter 3. Eighteen interviewees had no critical claim at all. The other sixteen interviewees displayed 9 different scores, which were divided into two groups (five intermediate scores and the top four scores).
[98] Spearman correlation.
[99] The associated p value is of 0.02.

whenever the proportion of analytical claims increases, the level of critical claims also increases at a medium rate. The coefficient of determination is of 0.14, meaning that 14% of the increase in critical scores is explained by the increase in analytical scores. Thus the *critical mentality* seems to really draw on assumptions and conclusions taken from the *analytical mentality.*

There are not only pharma companies that can be targeted by such critiques. Regulatory agencies and clinical guidelines are often focused on by critical views. For instance, McGoey and Jackson (2009) identified flaws in the UK's pharmaceutical regulations, whereas Petryna (2009) pointed to fundamental insufficiencies in the Food and Drugs Administration's procedures. Some analysts complain that regulations focus on drug trials and overlook the particularities of other studies (Watson and Gelling, 2012). One of my interviewees said that guidelines and ethics committees are frequently addressed in the lectures she gives to medical students.

> "*Knowing the operation of a committee must help students to submit proposals, right?* Oh, sure. This is what I tell them: 'Guys, you may like the guidelines or not. In my PhD, I showed that current guidelines (current Brazilian guidelines) are *not* adequate for the review of qualitative health research. However, in order to agree or disagree, there is no way: you have to know it and dialogue with what is available. I'm not claiming that you have to be subservient and always say amen, but you have to know and dialogue with what is available.'"
>
> (São Paulo/C3/Social scientist/05-11)

In this example, the interviewee has even conducted a study to scrutinize Brazilian guidelines, which according to her view, are inaccurate.

In this flawed research environment, many clinical trials, from a critical point of view, would eventually be unnecessary.[100] Hence, the strategic need for analyses and negotiations, as the same interviewee puts it.

[100] Pogge claims that many studies aims to explore drugs that are not *essential,* from a social and political point of view. See POGGE, T. 2007. Could glozalisation be good for world health? *Global justice: theory practice rhetoric*, 1-10.

"*And are you concerned with the fact that foreign companies are doing research in Brazil?*

No, I'm not concerned [...] I think that when we sit down to negotiate with foreign sponsors, they... be it foreign or national... they have to be seen as partners. So we'll sit down at a table and we'll see what the advantages are for you, what the advantages are for the country, the values, because, okay, everybody will get paid, that is okay [...] I think we have to have dignity to negotiate, indeed, something that is good and correct for everyone."

Interestingly, when it comes to pharma companies and CROs, the idea of negotiation acquires a special worth in the analytical/critical approach. The *technical mentality* tends to be very permissive, due to its respect towards companies. The *bioethical mentality*, by means of symbolic operations,[101] provides vague answers. Finally, the *communitarian mentality* tends to be antagonistic towards foreign companies. In spite of its sharpness, the analytical/critical approach seems to be endowed with a rare willingness to weight several aspects and search for negotiations and reflected decisions.

The following section addresses the sources of the critical approach.

6.2.3 Philosophical and historical sources

Three phenomena can be considered as motivators of the critical approach. Firstly, this mentality draws on the same sources that foster the analytical approach, but mainly on some recent examples of methodological failures in drug research.

Secondly, there is a psycho-sociological phenomenon related to the ways in which people react when confronted by homogeneizing contexts. As we have seen, ethics committees have turned into friendly environments for both the *bioethical* and *technical mentalities.* Thus, when it comes to concerns and claims, little space has been conserved for creativity and distinction. This circumstance acquired a very tangible shape during my fieldwork. In some interviews, after spending the five initial

[101] See Chapter 4, section 4.2.2.

minutes listening to the interviewee's claims, I could predict with great success what the following claims would be for the remaining forty or fifty minutes.

Insofar as mentalities can be subjected to globalizing processes, the primacy of the bioethical and technical approaches has eventually been transformed into a sort of ideological imperialism. We can even recur to the idea of behaviour, as it was defined by Arendt (1958/1998, p. 40): "[...] society expects from each of its members a certain kind of behavior, imposing innumerable and various rules, all of which tend to 'normalize' its members, to make them behave, to exclude spontaneous action or outstanding achievement." By analyzing the *discourse* of most of my South African and Brazilian interviewees, one could point to a sort of ideological behaviour. Ethics committees would eventually contribute to the emergence of the globalized "single thought" pointed to by Milton Santos (2000).

For many committee members, this ideological homogenization constitutes a guiding reference, for technical and bioethical concerns become a sort of guideline to be followed in the review of research protocols. However, some individuals (and especially those who privilege the *communicational rationality*) may react differently and look for alternative ideological pathways instead of complying with established norms. Opposing a *mental behaviour,* we would then identify a *mental rebellion.* This attitude does not lead to any search for isolation. On the contrary, people who look for distinctiveness have to engage in conversations and relations, the only means through which they can eventually grasp their uniqueness and voice their particular ideas. According to Arendt (1963, p. 116), "[...] it is the desire to excel which makes men love the world and enjoy the company of their peers, and drives them into public business."[102]

Finally, the critical mentality draws on a characteristic that is typical not only to ethics committees but to mass society: in homogenised contexts, distinctive actions can only be undertaken in the interstices of the system. In Scott's (1998, p. 58) terms, an alternative "social experience" can emerge in spite of the "formal order." To use Certeau's concepts, powerful "strategies" are growing bigger and bigger, leaving only small spaces in which wise "tactics" can emerge and search for preservation. We are dealing with a "[...] sort of cybernetic society, subjected to the Brownian movements

[102] As we shall see in the following section, this need for distinctiveness depends on personal, biographical factors.

of invisible and innumerable tactics. We would have a plethora of random and untameable manipulations, within a huge grid of constraints and socio-economic safeguards [...].” In ethics committees, these invisible tactics are possible because the review of projects continues to rely on the solitary reading undertaken by members.[103]

Thus, even though analytical/critical views tend to be suffocated by the bioethical/technical procedures of committees, a great deal of analysis and criticism is still possible when committee members realize their lonely *conversation* with research projects. Even though all committee members must comply with the standards of the ethical review model, this compliance does not come to forestall every possibility of distinctiveness. We can repeat Timmerman and Berg's (2003, p. 70) words to say that, for some individuals, “[...] the guideline is not a goal in itself but a *means*, acted upon in terms of their own aims and the local constraints structuring the situation in which the guideline happens to be placed.” Thus the critical mentality preserves the possibility of personal views, as claimed subsequently.

6.2.4 Personal formulation

As Figure 3.1 (page 71) shows, the emergence of a critical view depends not only on the adoption of the analytical mentality but also on a *mental* process that I name *personal formulation*. With this expression I am referring to individual pathways through which a critical view can be eventually obtained. In my fieldwork, out of 34 strong interviews (lasting at least 30 minutes), only four members voiced discourses that can be interpreted as analytical or critical (or both). In order to understand this phenomenon of personal formulation, it is interesting to look at these committee members' examples.

1. Physician (analytical discourse), Committee 6

He defines himself as an “almost retired” physician. He works in a medical field that is poorly explored by pharma companies. However, as a recognized physician (an

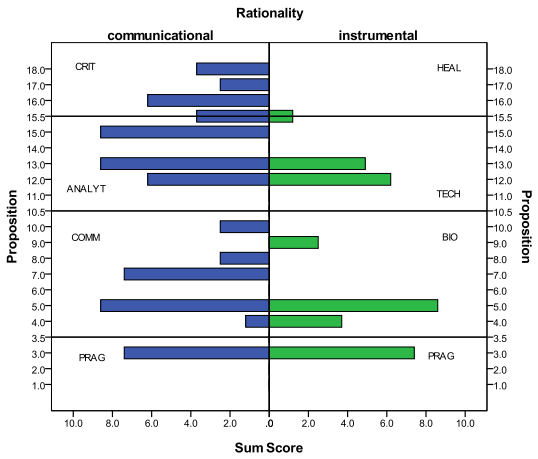
[103] On this point, see chapter 3, section 3.1.

opinion-leader), from time to time he receives invitations to be the principal investigator in some trials and does join some studies.[104]

2. Social scientist (analytical/critical discourse), Committee 3

She has acquired large experience in ethics committees (more than 10 years), having worked in different institutions. At the beginning, she used to review only qualitative studies but subsequently began to analyze drug studies as well. Nowadays, in addition to this committee, she is member of a committee that is also based in São Paulo. However, this second committee seldom receives proposals for drug studies. Therefore, she argues that her experience at committee 3 is important for her to keep in touch with drug trials, as she is "afraid of losing the practice."

Figure 6.3 – Discourse graphic n. 11



3. Social scientist (analytical/critical discourse), Committee 3

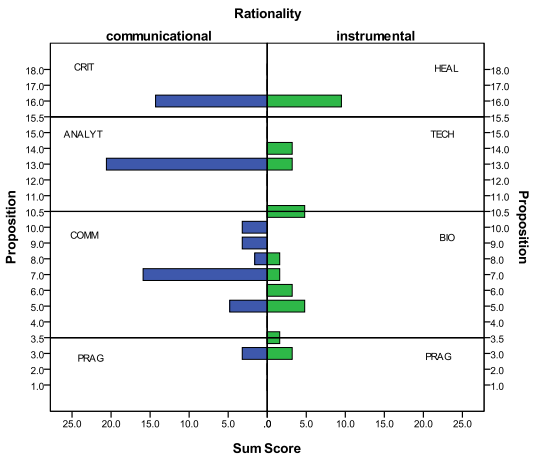
She is a social scientist and gives lectures on research ethics, sometimes for medical students. She is one of the new members of committee 3, in addition to being a new lecturer in the faculty.[105]

[104] The *discourse graphic* derived from this interview is in Chapter 5, Figure 5.1.
[105] *Discourse graphic* in Chapter 5, Figure 5.4.

4. Lawyer (analytical/critical discourse), Committee 3

He affirms to play a particular role in the committee due to his law background. Thus, physicians may consult him from time to time to address legal doubts. As the *discourse graphic* shows, his discourse is dominated by one group of claims (ANALYT13), according to which physicians are not the only ones who can assess drug trials proposals. From his point of view, in order to streamline the committee's operations, "[...] it would be important to have higher participation of people who are alien to the clinical staff of the hospital [...]."

Figure 6.4 – Discourse graphic n. 27



The fact that three of these members are based in committee 3 is important. Some outstanding, nationally respected physicians sit in this committee. Some five years ago, a new internal guideline was approved, stating that the majority of members should be non-physicians. Maybe feeling somehow threatened, the physician-members reacted by reinforcing their positions in the meetings. For instance, in one of the meetings I observed, some members (non-physicians) voiced concerns about physician-investigators who do not disclose their conflicts of interest, providing little information, if at all, about payments they receive from pharma companies. According to these members, a clear declaration of financial commitments should be a requisite for proposals to be accepted by the committee. After some discussion, physicians who were present in this meeting managed to suffocate the claim by arguing that this matter should be dealt with on a case-by-case basis. Arguably, such types of debates have been repeated over the last years, in this committee, as a consequence of the increase in the number of non-physicians. With more debate, there can be an expansion in the leeway for analytical and critical views to emerge.

It is difficult to identify the precise causes triggering the emergence of analytical and critical approaches. Here, statistical tests fail. However, there seems to be a common trait between the mentioned interviewees: they do not belong to the clinical trials' mainstream of their institutions. One of them is physician, having some relations with pharma companies and CROs; however, these relations are not frequent and ended up helping him to understand the ways in which the industry operates. The other members are professionals based in non-medical departments. Therefore, it seems that the analytical/critical view is more likely to emerge when committee members can look at trials with eyes of invaders, that is, as people who come "from the outside," bringing about social and political concerns to the realm of clinical research. By the way, this point was made by one of the interviewees focused on in this section. According to him, trials should also be justified on the basis of their social usefulness.

> "[...] it would be interesting if ethics committees had a more stringent stance, in order to oblige researchers to show the viability of their studies. To oblige them to either show this viability or have a broader view. I think people just say: 'Oh, that is okay, so it is fine.'
> *Okay, and that would imply a new section in the protocol.*
> No, I think within the protocol, that could be asked more directly, but I think physicians do not have this concern any longer because they're used to it. I think only outsiders are able to see that."
> (São Paulo/C3/Lawyer/04-11)

Here, we deal with one of the limitations of my study. Fully understanding the ways in which analytical and critical views are formulated would require more study and different types of interviews, exploring life stories, for example. In addition, it would be necessary to take psychological aspects into account, for even though the social and individual sides of mental life can be disentangled for the sake of interpretation, there are certainly connections between them.

The following section explores the critical approach to the ethics committee model.

6.2.5 Criticizing committees

Members who embrace the critical mentality also target ethics committees, pointing to flaws that can compromise their operation. The basic assumption is quite simple: clinical trials are thriving in South Africa and Brazil, making committees become too busy and obliging them to struggle to meet deadlines and accomplish tasks. One interviewee claimed that when she joined the committee, in 1993, the number of projects to be reviewed and discussed was quite small. Nowadays, discussions are sometimes sacrificed because the committee needs to rush its job.

> "I know they can't extend the time for the meeting [...] sometimes, he [the chair] would say: 'Just concentrate on the important points, the problem areas.' And I feel, for others around the table, to know about this trial... And the things that you may... There may be something inside of you that says: 'But something here is wrong,' but you can't pinpoint it, but if you discuss it in the meeting, somebody might pick up on it, people who have other expertise than yours [...]."
> (Cape Town/C6/Nurse/08-11)

Indeed, I observed meetings in five committees (2, 3, 6, 7 and 8). With the exception of committee 2, I realized that time is really an issue. Frequently, the atmosphere gets somewhat awkward, as people note that the final time is approaching while a considerable number of projects remain to be discussed. In the critical mentality, this problem is seen as a structural question, for it has to do with the national and global expansion of clinical trials. Thus, making the meeting longer would only be a palliative measure.

In Brazil, another structural problem is pointed out. As there are economic differences between regions within the country, ethics committees reproduce this imbalance, being more equipped in Southern states.

> "*So what would be the main goal of an ethics committee?*
> [...] to make sure that issues pertaining to the protection of subjects are guaranteed.

And do you think committees have been reaching this goal?

Committees or Conep?[106]

Both.

[...] Speaking of committees in general, I would say no. Considering the sample that we currently get at Conep, we've seen many problems depending on the location of committees in Brazil, depending on whether the place is resourceful (Southeast for example) or less resourceful, like for instance the less advantaged states. So I mean, there are problems in the system as a whole [...]."

(Brasília/C4/Bioscientist/04-11)

In the critical mentality, another flaw of the reviewing system is the precarious funding of committees. As a consequence, their work ends up being too abstract, for there is no contact to the actual procedures of studies. Thus, "[...] the oversight system turns a blind eye to the day-to-day work of trials" (DeBruin et al., 2011, p. 130).

"*And do you think that ethics committees, in the way they are organized today... Do you think they are capable of protecting people?*

No... because we... You know, we have to look at the paper but ethics committees rarely go out and look at what happens in the real world. So you don't... You get SAEs [Serious Adverse Events] reported, you get protocol violations reported, you look at the protocol, but that is all on paper, you know, and... I don't think there is a lot of ethics committees in the world that's got the money or the infrastructure or the resources or the people to physically go out and make sure that what you approve on paper, that is what is happening at the sites. So, no, I don't think... I don't think that is a South-African issue, I don't think it is an African issue, I think it is a worldwide problem...

Yeah, it is a global issue, yeah.

... that you just don't know, you approve it and then you have to trust that the sponsors and the investigators are going to do their job."

(Pretoria/C8/Lawyer/08-11)

[106] Conep is the Portuguese acronym for National Commission for Research Ethics, the central body that oversees the Brazilian ethical review system.

As this quote indicates, committees are said to be poorly funded, which prevents them to realize effective ethical assessments.

Finally, the critical mentality frequently turns into a weapon to attack the bioethical ideology that has dominated committees. Such stance is often expressed by means of a critique of the idea of informed consent, one of the *bioethical mentality*'s tenets.

> "*From your point of view, is there any part or section of the protocol that is more important?*
> [...] I actually haven't paid much attention to the consent forms, so I don't think that the consent forms are... I think they can be fetishized, you know: 'It is going to be okay if you have a good consent form' [...] So I tend to stay away from paying too much attention to the consent form."
> (Cape Town/C7/Social scientist/08-11)

> "I think there is too big a concern with only the issue of the informed and free consent form [...] Not all the reviews but many reviews always look exclusively at the relation to the patient, and few reviewers raise questions pertaining to sample sizes or the issue of patient recruitment [...] there seems to be a big concern with *formal* aspects, basically, with the consent form and with the patients' rights, whereas the methodological dimensions of research, you know, I think many reviewers consider them as a technical aspect, which, as they are not really within their expertise area, remain a bit overlooked [...] This is also a concern I have, you know, because research ethics involves not only the relation between researcher and patient but many things more."
> (São Paulo/C3/Social scientist/05-11)

Of course, the critical approach to committees generates more or less intense disappointments and frustrations. Committee members holding the critical mentality recognize that they somehow belong to a flawed global research system. At an individual level, the main question is thus how to find motivations to continue to work in these conditions.

"*After these years of work in the ethics committee... what do you think this work has brought to you, personally?*

[Laughter.] Well... I don't know, I think there are many things, you know. On the one hand, I get very tired with these reviews, they give me much work and so on, they often take away my leisure time [...] But I believe, honestly, that my work... this work is socially relevant [...] patients of SUS[107] depend on that health service. Most of them have few years of study, they ignore their rights, they are very vulnerable. So I always think: 'If we don't do a good job, this will get to a mother, for example, who is, say, functionally illiterate and will consent to the inclusion of her child into a study or not, for instance, which may involve a high risk for the child.' And what force does she have, in the health service, to say no, if she depends on that service? So I think it is a very relevant work [...]."

(São Paulo/C3/Social scientist/05-11)

As this quote shows, the communitarian approach can become a sort of ideological scapegoat. As the critical mentality highlights unsolvable problems, members may look for motivations in the altruistic and emotive notions of the *communitarian mentality,* therefore imparting some vibrant hues to an ideological picture that might eventually become dull and dry.

In spite of its sharpness, the critical approach remains a diluted social phenomenon, being unable to generate partnerships and collective actions, as we shall see in the following section.

6.2.6 Political implications of the critical mentality

The critical mentality perpetuates the political weakness verified in the other *communicational* mentalities*:* it has been unable to underpin organized, collective actions. In this way, it depends on individual stances and *personal formulations.* Nevertheless, there seems to be special moments in which critical claims get more likely to be voiced. Frequently, these are either moments in which big scandals come to light or moments of widespread debates.

[107] SUS is the Portuguese acronym for Unified Health System (*Sistema Único de Saúde*), the Brazilian public and universal health system.

In Chapter 3, we remembered the South African national policy for anti-retroviral drugs, which was adopted in 1997 and provoked a bitter legal reaction from pharma companies. At that moment, the story turned into a national issue, and many people came to blame what they saw as an unfair, interested attitude of multinational drug companies. Quickly, the *communicational rationality* and its *mentalities* were activated, from the pragmatic to the critical approach, in an ideological chain reaction.

Another example comes from Brazil with its current effort to renew and streamline the ethical review system. As the process opens up much leeway for decisions to be taken and changes to be implemented, all the *mentalities* awake. The critical approach is then mobilized to point to flaws that according to some analysts, have compromised the Brazilian system. The National Commission for Research Ethics (Conep) has been one of the main targets of critical claims. Indeed, some of my interviewees think that Conep should not review protocols, decentralizing some of its tasks and allowing itself more time for overseeing the national system.

> "Conep [...] has its own problems pertaining to excessive amount of work, little time to deal with issues that could modify the system, making it more flexible and more controlled, which could also favour the committees' work locally. I mean, there are certainly problems to be tackled."
> (Brasília/C4/Bioscientist/04-11)

> "*It seems that one of the ideas for Conep will be the decentralization, you know... Does this idea sound interesting for you?*
> [...] *Conep must stop reviewing from 80 to 100 projects per month*. It must stop [...] Because it looks like a giant ethics committee doing that. And Conep is not a giant committee. It is the only national commission with specific functions. A group of people that is discussing guidelines on research ethics, which will be valid for the whole country, should not undertake this discussion in the remaining time, searching for one hour for this discussion because that is not possible in the meeting [...]."
> (São Paulo/C3/Social scientist/05-11)

When Conep was created, in 1996, bioethical concerns dominated the process, especially via the influence of the Brazilian Society of Bioethics. The two-layer system,

with studies considered as “special” being reviewed by both Conep and local committees, was aimed to enforce compliance with ethical principles. The claims quoted above, however, ask for (*analytical* and *critical*) stringency from Conep, which should make sure that committees are able to fully assess the clinical studies’ worth. Therefore, analytical and critical claims can also be fostered in particular historical contexts. Even though these approaches display very low levels of institutionalization, they continue to have their political and social efficacy.

From the viewpoint of mental life, then, the critical mentality is a troublemaker, in the sense that it identifies problems whose solution requires drastic measures. This is the only approach for which the idea of transformation is really decisive. It admits that the crises experienced within the current schemes of clinical research cannot be solved without deep changes in the funding, conducting and overseeing of trials. Hence, some claims such as the one voiced by Pogge (2007, p. 3), according to whom health research needs “a concrete and specific reform plan,” which should be inspired by political considerations. Broad issues are stressed also by Petryna (2009, p. 197), who affirms that “[...] we need alternative international frameworks for pricing and intellectual property, frameworks that address the needs of the developing world and thus provide a more cogent social imperative.”

Thus the critical mentality depicts our historical moment as a *critical* one, for solutions would not be possible without radical shifts in the global research scenario. Seen from this perspective, the globalization of trials is framed as a research system fraught with problems, a circumstance that asks for a new research system, which would probably stress national needs and solutions.

In complete opposition to this stance, the *healing mentality* tends to appease tensions and avoid controversial issues, as we begin to analyze in the next section.

6.3 THE HEALING MENTALITY

Each mentality described in my study foregrounds one key concept, as the following table summarizes.

Table 6.1 – Mentalities and their main concepts

Mentality	Concept
Pragmatic	Interest
Bioethical	Fairness, justice, non-maleficence, beneficence...
Technical	Standards and progress
Communitarian	Compassion[108]
Analytical	Methodological flaw
Critical	Crisis

It is time to add a new row to this table by saying that for the *healing mentality,* the main concept is *therapy*. However, this approach has a particularity, for this concept does not seem to suffice. It would be necessary to refer to the idea of medicines, even though, as it is clear, this is not an idea as such but a word used to describe a tangible object. Thus, the healing mentality cannot exist without being constantly oriented towards concrete therapies, whether they appear in the form of medicines, devices or medical procedures. From this concrete consideration, however, it rapidly goes towards very broad ideas, stressing universal potentialities of research.

6.3.1 Global solidarity

In the same way that the *critical mentality* depends on analytical concerns, the healing approach inherits some notions formulated by the technical approach. The main example is certainly the technical idea according to which research brings about advantages for every type of groups and individuals. In the *healing mentality,* this idea becomes the basis of a discourse in which the search for therapies goes beyond

[108] As explained in Chapter 4, the idea of compassion is an underlying concept, for it is not openly voiced by holders of the *communitarian mentality.*

individual preferences and political projects. This point was made, for instance, in an interview in which the question of biological samples being exported was addressed.

> "*For you, this is not an issue.*
> It is not an issue sending it out, no. And also, I don't care about what they do with it afterwards. If I am giving my blood sample, I've given it, it's out of my body, it can't come back and they can't do anything to me. What does it matter? As far as I am concerned, it is for the benefit of the mankind [...]."
> (Cape Town/C7/Lay member/05-11)

Acknowledging that clinical research can be advantageous for the "mankind" implies the admission of "an undifferentiated global epidemiological space," to use Lakoff's (2005, p. 32) words.[109] The idea can grow bigger and bigger because, undeniably, there is indeed a common trait to all human beings, which is the fact that every-*body* possesses a physical *body*. Thus the healing mentality is also informed by the "one-ness of man-kind," as this fact was described by Arendt (1958/1998, p. 45-46).

At the core of the healing approach, we find this humanitarian notion whose consequence is the avoidance of tensions for the sake of a communistic view. "Behind the 'harmony of interests' stands always the 'communistic fiction' of one interest, which may then be called welfare or commonwealth" (Arendt, 1958/1998, p. 44 note 36). From this viewpoint, the globalization of clinical trials is seen as a natural development of the history of humankind in its secular fight against disease. This is the source of several claims pointing out the therapeutic purposes of clinical research.

6.3.2 Clinical trials and therapy

The healing purposes of trials can be voiced in two related, albeit different, ways. Firstly, there is a range of claims admitting that by means of their participation in

[109] By the way, the idea that health problems cross out national and social frontiers has inspired some interpretations such as the one which stresses the existence of "diseases of poor people." In this way, poverty and sickness would be comparable no matter what the context is.

clinical studies, people can improve their health condition. Therefore, there would be direct advantages in research participation.

> "*In your opinion, what is the main goal of clinical research?*
> To generate results that can benefit the population and bring about, on the other hand, for those who investigate, some rewards over the product they propose. So let's us make clear that, if possible, there must be benefits for both sides, for the research subject and the researcher [...] So I mean, the ideal situation would be a win-win relation between all the parts involved.
> *Okay. And the subjects' benefit would be therapy.*
> Therapy; access to care that they could not have when they are in a less resourceful hospital; there could be a more frequent assessment of their disease condition, which they wouldn't have in a less resourceful hospital; a more multiprofessional view; access to examinations that they couldn't generally have. So in fact, research subjects almost always have benefits in that sense, in terms of health assessment, you know, even though they don't necessarily have benefit in terms of the effects of the medicine under study."
> (Brasília/C4/Bioscientist/04-11)

> "The HIV trials and the TB [tuberculosis] trials, clinical trials, that we're doing now are done quite differently from, say, a cancer drug trial. HIV and TB trials now, the ethical requirements are far stricter; things like having a community advisory board, most of your HIV trials have to have that now [...] Plus your standard of care has to be good. I mean, in your prevention trials, you've got to provide treatments for SAEs [Severe Adverse Events], you've to give very good HIV test counselling... So there is very good standard of care in those trials [...]."
> (Cape Town/C7/Bioethicist/07-11)

Thus, one considers that participation in a trial would eventually become a sort of alternative health service. In addition to being mobilized by committee members, these ideas may be voiced at research sites. For example, in her study about clinical trials in the United States, Fisher found out that the argument is often used by the research staff in order to convince patients to join clinical studies. These professionals

would then stress "[...] the benefits that individual patient-subjects experience as a direct result of their participation in drug studies" (Fisher, 2009, p. 199).

The second way to voice the healing capacity of trials is to actually focus on the production of medicines and therapies, seen as the ultimate goal of studies. Even though people acknowledge that the means used in trials may be controversial or problematic, it is as though the ends of trials were powerful enough to justify these troubles.

> "*In your opinion, what is the main goal of clinical research?*
> [...] It is to develop [pause] better clinical treatments. And it depends on what you mean by clinical, yes. Clinical, to me, means medical, means clinical context, so it means either pills, injections, it means treatments, it means techniques, surgical techniques, it means equipment or whatever else it is [...] So I think the problem is to do that better, more effectively, possibly more cheaply, because it is important to do things more efficiently [...]."
> (Cape Town/C7/Social scientist/08-11)

> "*In your opinion, what is the main goal of clinical research?*
> [...] [Laughter.] From which point of view?
> *What do you mean?*
> [Laughter.] Do you mean, from my point of view?
> *No, in general [laughter].*
> In general? From my point of view, research is to improve the health system, to improve the lives of people, to fight disease, to fight illness [...] I mean, what other opinion can one have of clinical research? Anyone knows what clinical research is about. It is about improving lives, improving medicine, improving treatments. I just wish that they can get on with some of these treatments so I can be treated [laughter]."
> (Cape Town/C7/Lay member/05-11)

> "[...] Typically, what happens in the pharmaceutical industry... You're testing medications. So it is about response, it is about getting better, it is working towards a positive outcome. You're starting out with sick people and you want to heal them [...]."
> (Pretoria/C8/Bioscientist/07-11)

Healing patients is a major concern for the healing mentality. Nevertheless, even in the case of diseases with no cure, research would still be useful insofar as new drugs could prolong some patients' lives and enable them to live better. As a result, healing claims are often exemplified with references to medicines to fight cancer and other rare diseases.

> "*In your opinion, what is the main goal of clinical research?*
> [...] To help with the discovery of new treatments to treat... whatever, diseases, especially your serious diseases like your cancers, your HIVs, your malarias, things like that, you know. You have to try and find cures for incurable diseases and, obviously, better what we have and try and make advances in what is already available, because you often have effective medication but it's got a very high side effect profile and things like that [...]."
> (Pretoria/C8/Lawyer/08-11)

> "*In your opinion, what is the main goal of clinical research?*
> [Pause.] Well, it is for your and my well-being. That is what clinical research should be all about. It is to enhance health [...] I was always sort of sensitive and nervous about cancer protocols [...] the reason why you often saw another emphasis in cancer research, which is prolonging people's lives but it is also directed at a better quality of life, 'cause these people often don't have a good quality of life, because of the toxicity of all these drugs. So, yeah, in a way, I would think, any clinical research should also keep quality of life in the back of their heads, which I think they do. You know, why, for example, combining drugs into one tablet? That protects you from four or five tablets that you carry and etcetera etcetera. And it is often, you know, that two drugs will perform the same but the one with the least side effects will be the favoured one, which contributes to quality of life [...]."
> (Pretoria/C8/Bioscientist/07-11)

The emergence of mentalities also depends on social and historical factors. The healing mentality is more likely to appear in situations of health problems and epidemics. South Africa, for example, has been fighting, for many years, tuberculosis and HIV, which have infected large populations in the country. As a consequence,

healing claims can be voiced to depict trials as one therapeutic alternative for South Africa.

> "*Over the last years, there has been a big expansion of international clinical trials in countries like South Africa.*
> Hm hm.
> *Do you think that this growing number of protocols is really important and necessary?*
> For South Africa? Yes. Because we have a big problem. If you think about HIV alone, the companies put a lot in HIV research coming out of this country [...] That is very important [...]."
> (Cape Town/C7/Lay member/05-11)

> "*In your opinion, what is the main goal of clinical research?*
> [Silence.] Hm. We could say, improve the situation of the patients [...] Here in the country, very much in need is... There are lots of studies going on HIV-TB-malaria (malaria not so much in South Africa but HIV-TB) and there are lots of open questions that need to be answered outside of industry sponsors' studies: what is the appropriate dosing regimen or appropriate dose, the best way of treating patients [...]."
> (Cape Town/C6/Bioscientist/08-11)

Such statements can be swiftly combined with technical claims, and the final result is the ideological justification of global studies conducted by pharma companies and CROs.

> "*But do you think it is important for Brazil to take part in this kind of [international industrial] research?*
> I think so [...] because, look, these are new medicines that should be tested in our population, because nowadays pharmacogenetics is very important. We know (for many reasons that we don't have to discuss here) that medicines have different effects in different populations, right? And why? Because there are genetic variations that sometimes may... especially in certain enzymatic complexes... There are populations that metabolize a certain medicine more quickly, so it remains in the organism for a

shorter time, whereas other populations are slower. So there is a vast range of issues that make it important to test it in several populations, you know. I think there is no doubt that yes, it is important for Brazil. There is no doubt. For every country [...]." (Brasília/C4/Bioscientist/04-11)

Justifying the globalization of trials with reference to ethnic factors, like this interviewee did, is a discursive strategy used in some studies (Marschner, 2010, Cummings et al., 2011). In this way, the *technical mentality* gets covered by a moral shield. On the one hand, there are bioethical claims pointing to benefits outpacing the risks of trials. On the other, there are healing claims foregrounding the universal duties fulfilled by clinical research.

In the following section, we focus on the ideological sources of the healing mentality.

6.3.3 Philosophical and historical sources

In the mid-1980s, Burroughs-Wellcome (subsequently called GlaxoSmithKline) conducted a clinical trial to test the efficacy of a compound named zidovudine (or simply AZT) to treat HIV-Aids. Results were outstanding, for AZT was the first drug to display positive effects at fighting the new disease, helping to prolong some research subjects' lives. Prospects proved so auspicious that the trial was actually terminated so that patients on the placebo arm could access the real drug. From the first tests in clinical settings to the market, the process took twenty-five months, a very short time in the field of drug research.

This story, recalled in Epstein's (1996) book, reminds us of a relevant circumstance: in some clinical studies, certain participants do improve their health conditions. Over the last years, many social actors have learnt to frame clinical trials as a potential source of therapies and useful drugs. That is why, for instance, some groups campaign for the right to enrol in trials (Epstein, 2007) or the right to access medicines just tested in clinical studies (Petryna, 2009). The healing mentality is one of the consequences of this assumption, according to which trials have therapeutic powers.

The issue is as old as clinical research itself. Fox's (1959/1998) study focused on a medical ward in which research was conducted without many of the sophisticated equipments and notions that are accessed by today's investigators; yet, even in those conditions, a certain amount of care and therapy could be gleaned from perilous experiments.

It is not worth discussing here the complex issue of placebo effects and measurements of health and illness. From a sociological standpoint, there is no need to ask whether the healing mentality would express a wise perspective or simply a discourse voiced by innocent dupes. Even if clinical trials are devoid of "therapeutic efficacy," the emergence of the healing mentality shows that they are full of "symbolic efficacy," to use Lévi-Strauss (1958/1974) classic expression. In other words, clinical trials have been given social sanction to figure in the list of recognized therapeutic alternatives. As some studies have shown (Benoist, 1989, Etkin, 1988, Lefèvre, 1991, Van der Geest et al., 1996), medicines are effective not only because they may have positive clinical outcomes, but also because they are collectively expected and hoped to be effective. As claimed by Van der Geest and collaborators (1996, p. 167): "Efficacy is brought about in a context of belief and expectation and through social communication and interaction."

Another phenomenon allowing the formation of the healing mentality was explained by Arendt. Modern society has been marked by massification and behaviour. Ancient concerns with political life and distinction have been replaced by the sheer concern with the maintenance of the individual life. Thus, discourses tend to conquer almost immediate social approval whenever one foregrounds issues such as biological preservation, health, well-being, physical satisfaction, among others. "[...] it is the life process itself which in one form or another has been channelled into the public realm" (Arendt, 1958/1998, p. 45).

This conception tends to be reinforced in our days, following to advances in fields such as genetics, stem cells, assisted reproduction or neurosciences. Society turns hopeful eyes to biosciences, which promise to explain the hidden causes of every behaviour, disease or thought (Habermas, 2008). By plunging into these explanations, one would expect to understand human beings in their most fundamental characteristics, those which do not depend on nationalities, contexts and particularities. The globalized nature of many medical studies enhances these hopes, a

trend that is also verified in clinical trials. There would be a global solidarity promoted by global research, insofar as everyone may at some point be a research participant or the consumer of a final medication. In the healing mentality, technical and humanitarian claims are mixed up to formulate a powerful discourse. As Lakoff (2007, p. 65) argued: "For contemporary theorists of the symbolic efficacy of biomedicine, the shared sense of the authority of scientific knowledge and its techniques produces its own healing effect."

There is another important idea underpinning the healing mentality. Since Adam Smith (1776/1979), the image of a market guided by an "invisible hand" circulates. Thus, one admits that balances and equitable distributions are generated by the spontaneous mechanisms of market, rather than being triggered by massive policies. Through simple, administrative procedures, national and global schemes, including health research, would acquire desirable formats.

> "A complete victory of society will always produce some sort of 'communistic fiction', whose outstanding political characteristic is that it is indeed ruled by an 'invisible hand', namely, by nobody. What we traditionally call state and government gives place here to pure administration […]" (Arendt, 1958/1998, p. 44-45).

The healing mentality cannot be sustained without this underlying assumption of spontaneous market mechanisms. If research and technology have potentially humanistic, universal effects, as it is admitted, then, in the long run, current imbalances and inequalities can be sorted out thanks to distributive tendencies embedded in research and technology themselves. As a consequence, holders of the healing mentality do not need concepts such as state, economic actors, companies, pressure groups, among other terms formulated by the political thought. Eventually, the discourse reaches heights of abstraction and all kinds of processes, whether they are biological or social, are framed as natural events. Thus the healing mentality has been one of the main ideological frameworks responsible for the "unnatural growth of the natural," to use Arendt's (1958/1998, p. 47) expression.

In addition to these philosophical and historical sources, the healing mentality has been composed and diffused through the effort of big companies engaged in clinical trials, as I claim in the next section.

6.3.4 Industrial formulation

All the mentalities described in my thesis derive from widespread processes. One can say that instead of being planned and promoted, they are the result of diffuse processes, which converged to finally form a set of cogent and meaningful claims. However, the healing mentality has one crucial particularity: it has been adopted by pharma companies and CROs in their official discourses. These companies, by means of claims strategically formulated and diffused, strive to present healing ideas to many types of social actors.

For example, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), an entity which gathers many companies and national pharmaceutical associations, presents its goals, in its website,[110] in the following fashion: "The IFPMA advocates policies that encourage discovery of and access to life-saving and life-enhancing new medicines to improve the health of patients everywhere." Another example comes from a report ordered by the Association of Clinical Research Associations (ACRO) and prepared by a consulting firm; in this document, the following statement is found:

> "Clinical research [...] provides benefits well beyond the direct effects of the therapeutic intervention. Patients get access to a standard of care that might otherwise be unavailable, investigators are exposed to advanced medical techniques and the larger society benefits from improved health infrastructure and economic development" (Voi Consulting, 2009, p. 15).

Such claims are frequently echoed in many social milieus, including academic ones. In a 2006 paper, for example, Wood advanced the following conclusion: "In spite of the criticism directed toward them, pharmaceutical companies have produced a

[110] http://www.ifpma.org/

substantial public health benefit" (Wood, 2006, p. 618).[111] Indeed, the trials industry seems to be looking for different media in order to convey the humanitarian, public nature of their clinical studies.

Eventually, the companies' official discourse depicts a pharmaceutical universe in which, beyond practical goals, the universal fight against disease would prevail. These ideological efforts are in tune with the tendencies of our historical period, in which companies, but especially huge multinational corporations, launch foundations and non-profit projects in order to convey their "corporate social responsibility" (Pereira, 2007). The phenomenon is already visible in the pharmaceutical domain, in which the industry "frames its work [...] in terms of philanthropic or humanitarian priorities" (Fisher, 2009, p. 213).

In the previous chapter, it was argued that in the procedures of modern science, knowing is highly dependent on making. In other words, scientific knowledge is derived from experimental situations carefully produced and controlled by scientists. These blends of knowing and making are at the core of the *technical mentality.* Pharma companies and CROs, seen as clinical researchers, reproduce this feature of modern science. In addition to conducting studies to understand illnesses and drugs, they also have to produce experimental situations, in two ways. Firstly, they need to construct concrete research networks, recruiting investigators and settings, contacting regulatory agencies, outsourcing some research procedures, and so on. Secondly, they have to build up ideological scaffolds to sustain all these concrete structures.

On this second point, Lakoff provides us with an example. Focusing on a clinical study conducted in Argentina at the end of the 1990s, he showed that Genset, a biotechnology company, strived to teach physicians about the existence of bipolar disease, a condition that was not medically recognized in Argentina at that moment. It was necessary to show that bipolar disease exists objectively, that is, it can be diagnosed regardless of national particularities. If the condition can be verified in several countries, the company argued, then a global clinical trial should be undertaken in order to derive therapies to fight the disease globally (Lakoff, 2005). Thus, from Genset's point of view, before undertaking the actual clinical study, it was

[111] At the end of this paper, the journal was careful to inform the reader that the author had been receiving consulting and lecturing fees from some pharma companies. The information is important, even though one cannot completely sure that these relations triggered the positive Wood's view about pharma companies

necessary to ideologically prepare the field, “producing” the idea of a certain disease and convincing people that it was worth fighting.

These ideological efforts are difficult to grasp, especially because they are less evident than the concrete research networks constructed by companies. Perhaps, things become clearer if turn our eyes, for a while, toward the final stages of drug development. Frequently, advertisements and even physicians’ discourses may impart a magic image to medicines, be it in a direct or indirect way (Fisher, 2009, Frazzetto, 2008). Publicity campaigns may stress not only the superiority of particular medicines but also the seriousness of pharma companies (Busfield, 2006).

Coming back to the domain of clinical trials, the conduct of studies can also be used to signal the companies’ commitment to science, progress and therapy. As Frazetto (2008) claimed, the efficacy of some drugs (for instance, antidepressants) is sometimes publicly contested, but the image of medicines can eventually be improved, for companies can always counter-argue that research is underway to verify the accuracy of contestations. By the way, pharma companies and CROs have become quite responsive to criticisms over the last years. For example, as Will and Moreira (2010) explained, companies have reacted to claims according to which the over-controlled environment of trials was not conducive for testing medicines to be used in the real world. “In this context, there has been an increase in trials designed to assess ‘effectiveness’, defined as the benefit of an intervention under usual conditions (rather than the ‘ideal’ conditions produced in a highly controlled efficacy trial)” (Will and Moreira, 2010, p. 1).

Shaping norms and guidelines is another way to diffuse mental frameworks, for as Luhman (1972/1983) explained, standards and guidelines are powerful instruments to normalize and transmit social expectations. By means of lobbying activities, pharma companies and CROs strive to standardize national legislations. According to Timmermans and Epstein (2010, p. 76): “Over time, especially in the United States, the power of governmental standardizing agencies has declined and the power of industry standard setting agencies has grown.” International guidelines are also subjected to these trends. The Declaration of Helsinki, for instance, has undergone several amendments, as a result of companies’ pressures (Shah, 2006). Finally, pharma companies have been preparing ethics handbooks to guide the ethics committee

members' work. In my fieldwork, for example, one Brazilian interviewee declared to keep an ethics handbook prepared by Merck in her personal files.

Not to forget is the role played by the media in these ideological efforts. For instance, the media was interestingly mentioned by one of my interviewees.

> "*In your opinion, what is the main goal of clinical research?*
> To improve the people's quality of life.
> *Hm. To improve the quality of life. Do you mean, medically, from a medical point of view?*
> Yeah, I mean, to improve the people's health.
> *And do you think that this goal has been reached?*
> [Pause.] Yes... Oh, surely, there has been much progress, right? But I don't draw on my experience in the committee but on what we see in the media, because there is always news about studies... This is interesting, you know, people don't know the work of ethics committees very much, but the outcomes of studies are circulated by the media [...]."
> (São Paulo/C3/Lawyer/04-11)

Thus the media is sometimes decisive at making healing notions widespread. In this case, the circulation of news made the interviewee conclude that clinical trials aim to "improve the people's health."

Indeed, the global diffusion of healing claims seems to be the product of a huge effort of ideological engineering. As some authors have noted (Fisher, 2009, Petryna, 2009, Shah, 2006), pharma companies and CROs always hasten to point out the beneficial effects of trial participation. The pharmaceutical industry claims that studies are specially relevant in poor areas "because in these regions clinical trials have become social goods in themselves," insofar as "they provide healthcare where there is none […] and medical relief for participants' specific ailments for the duration of the trial" (Petryna, 2009, p. 42).

We are dealing here with series of ideological reversals. In a first moment, the *technical mentality*, drawing on a plethora of individual cases and particular diseases, claims that these particularities are not very relevant, for the general, abstract knowledge gleaned from such observations is what really matters. In a second

moment, the *healing mentality* affirms that general knowledge is important, but invites us to pay attention to particular diseases and the sufferings of humankind. Eventually, one can foreground either the idea of knowledge (and the image of accuracy it conveys) or the idea of disease (and its associated humanitarian image), but the discourse never leaves a very general, intellectual, conceptual level that is typical to the *instrumental rationality.* According to Arendt, it was Plato who introduced the possibility of philosophical reversals, showing that "[...] reversals within the course of intellectual history no longer needed more than purely intellectual experience, an experience within the framework of conceptual thinking itself" (Arendt, 1958/1998, p. 293).[112] Presently, ideological reversals can also serve the political purposes of global economic actors.

The ultimate result of these ideological operations and reversals would be the diffusion of beliefs and trust pertaining to medicines and clinical trials. For instance, I quote the words of a lay member interviewed in my fieldwork.

> "*After having worked in an ethics committee, has the way in which you see medicine and drugs changed?*
>
> Look, before working here, I used to think about it in a certain way, and now I think differently. And what does it mean? Now I have more knowledge, you know. I didn't know how medicines arrive here. 'They're selling the medicine in the United States but not here. Why?' So I didn't understand the bureaucracy, the technical part... I didn't know. Now I know that you don't do it overnight. There are criteria that must be adjusted. And my knowledge has improved a lot [...]
>
> *Is it possible to say that now you trust more medicine and drugs?*
>
> Oh, it is. It is. It is, because I know what physicians are doing, the drug has come through here, it's been analyzed, studied, approved, we look at the patients, they're there, if there are any problems we can go there and talk to them [...]."
>
> (São Paulo/C3/Lay member/05-11)

Thus the conduct of clinical studies, but also the reviewing tasks of ethics committees, underpin the idea that a huge, international healing program is

[112] Arendt referred to the Platonian insight that the body and earthly life, rather than the soul and after life, inhabit a shadowy, obscure world.

underway. Even though I quoted one layperson's words, physicians and scientists would not be protected from such beliefs, which would assume a different form in their case. By listening to some claims voiced by these specialists (some of them quoted in the previous chapter), it is hard not to have the impression of faith in scientific standards, statistical tools and biological notions. In addition, claims formulated by pharma companies and CROs are rapidly channelled into medical conferences, and physicians end up becoming key diffusers of an official medicalized rationale (Almeida and Bicudo, 2010). This function may be further enhanced when physicians also play the role of clinical investigators, for it seems unlikely that physicians and their research staff, when recruiting patients for trials, impart a negative impression of clinical studies to potential participants. In her study, Fisher (2009, p. 193) noted that the research staff actually engages in "education" efforts, letting patients know the advantages of clinical trials, and stressing mainly "[...] the impact of subjects' participation on the future of medicine."

From the point of view of the communicative action's theory, clinical trials can be seen as a set of meaningful actions through which the belief in scientific and ethical norms can be constructed. Thus, one can invoke Certeau's (1990, p. 262) words: "Nowadays, it is no longer enough to handle, carry and refine beliefs; it is necessary to analyze their composition, for one wishes to produce them artificially [...]."

It seems that this artificial production of beliefs has been quite successful. For example, the following table presents the most popular claims voiced in the interviews I conducted.

Table 6.2 – The six most widespread claims

voiced by the committee members interviewed

Claim	Mentality	Number of interviewees	Proportion[113]
"Clinical research aims to generate useful medicines and therapies"	Healing	31	73%
"Research subjects need to be protected against physical harms"	Communitarian	30	71%
"There are financial interests involved in clinical research"	Pragmatic	29	69%
"In order to be protected, research subjects need to receive full information about the studies' goals and procedures"	Bioethical	24	57%
"Guidelines and legislations help to keep the ethical nature of clinical research"	Bioethical	23	54%
"Clinical research aims to generate and improve knowledge of drugs and illnesses"	Technical	22	52%

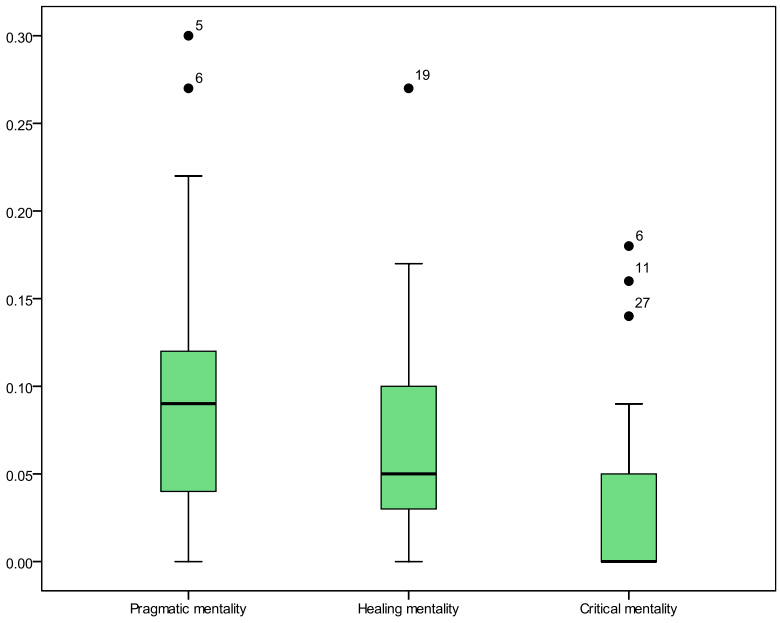
There is no surprise in the fact that the third position is occupied by a pragmatic claim (spontaneously voiced by 69% of my interviewees), for the contents of the *pragmatic mentality* are largely recognized. The fact that a communitarian claim appears in the second position (71% of my interviewees) is not strange either, for here we are in a region of the mental life where pragmatic and communitarian claims overlap. Nevertheless, it is interesting to find a healing claim in the first position, having been voiced by 31 interviewees (73%). This circumstance reflects, on the one hand, the force of the historical and philosophical sources from which the healing mentality springs (as explained in the previous section), while expressing, on the other hand, the *industrial formulation*'s efficacy. By repeating healing claims in several social milieus, pharma companies decisively strengthen the force of this approach.

We are dealing with a twofold process. On the one hand (as can be seen in Figure 4.2, page 110), healing claims do not seem to constitute big proportions of

[113] Percentages were calculated over 42, the total number of interviews I conducted.

people's discourses. On the other, the table above shows that at least a small number of healing claims are accepted by a large set of committee members. Indeed, even those members who voiced discourses strongly marked by the analytical and critical approaches also advanced a small number of healing claims. Thus, it can be said that the healing mentality has turned into one of the elements of *background knowledge.*[114] In other words, the therapeutic usefulness of clinical research came to figure in the list of taken-for-granted ideas, which are protected from debate and suspicion. This phenomenon can be shown with statistical tools as well. Let us consider the following boxplots.

Figure 6.5 – Discourse boxplots: pragmatic, healing and critical mentalities



There is no statistically significant difference between the *healing* and *critical mentalities.*[115] However, an interesting finding comes to light when one compares them to the *pragmatic mentality.* On the one hand, there is no significant difference

[114] See Figure 3.1 on page 71.

[115] Firstly, by using the Friedman's test (K related samples), I compared all seven mentalities and discovered a highly significant difference for the whole sample (p value less than 0.0005). In order to verify where the difference really lies, I performed the Wilcoxon's test (2 related samples), comparing *mentalities* individually.

between the healing and pragmatic approaches (p=0.14). On the other, I verified a significant difference between the critical and pragmatic approaches (p less than 0.0005). In conclusion: considering the proportion of claims in my interviewees' discourses, the *healing mentality* has reached the same ideological level of the *pragmatic mentality* (*background knowledge*) while the critical approach remains at a significantly inferior level.

I would not deny that most clinical studies may end up having pharmaceutical or therapeutic implications.[116] However, this is just an idea or, more precisely, a *claim,* which is devoid of meaning when looked at in isolation. It is important to verify how claims are combined and put to work in the framework of different *mentalities* and *rationalities.* For holders of the analytical/critical approach, healing claims are quickly tamed by considerations that go beyond the immediate purposes of trials, seeking to understand social and political structures. For holders of the technical/healing approach (as well for those who embrace the *communitarian mentality* and suffer the effects of *mental colonization*)*,* healing claims are fundamental components of an ideological framework stressing the relevance of science, progress, therapy, global research, scientific knowledge, among other ideas.

The healing mentality is pushed into the *background knowledge* by means of repetitive discourses voiced by the trials industry in different media (*industrial formulation*). Nevertheless, it constitutes an atypical component of this *background knowledge.* As we saw in Chapter 3, the *pragmatic mentality* is composed by simple claims deriving from practical observations that do not depend on specialized skills or knowledge. Pragmatic concerns are largely meaningful not only because they are easily understandable but also because, in a sense, everybody participates in their formulation by taking them into account, understanding them, and assenting to their *facticty*. Healing claims certainly need this type of social recognition but, to a great extent, their initial formulation and subsequent diffusion have depended on ideological efforts undertaken by the industry, which strives to make the therapeutic advantages of trials resonate in the media, medical conferences, state institutions (lobbying activities), research settings, among other milieus. The fact that in both South Africa and Brazil, a large number of committee members voiced healing claims

[116] As a member of society, the author of this study cannot avoid holding some notions of *background knowledge*.

as taken-for-granted ideas may be signalizing that as Bufield (2006, p. 302) claimed, the "ideological power" of the industry needs to be taken into account.

The following section aims to analyze the relationships between the healing and communitarian mentalities.

6.3.5 Healing mentality and mental colonization

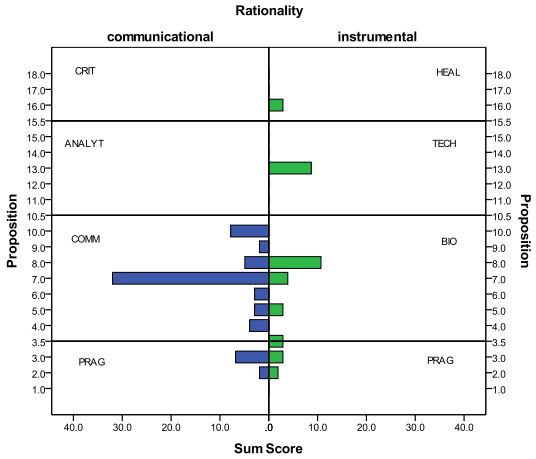
As explained in the previous chapter, I am calling *mental colonization* the process through which one or more claims, which are initially crucial to the *technical mentality*, "migrate" and come to occupy a central place for the holders of the *communitarian mentality.* Although this migration generally happens with claims of the technical approach, it can also happen to healing claims. In the next quote, I am breaking one interviewee's reply in different parts:

Question	"*And with these differences [between academic and industrial research], do you think it is important for Brazil to take part in international protocols?*
?	I don't have any doubt it is. It is very important for several reasons...
Technical	Technology transference, which is something we struggle for all the time in Conep.
Communitarian	So we don't want researchers only to come here to collect blood from Brazilian people and take it out. What we want them to do [...] is to come here, collect blood, take it out but to make all the information that comes from that blood available to all the Brazilian scientific community, as well as for patients, right? [...]
Technical	Apart from that, it is new information, it is knowledge,
Healing	it is new medicines, it is new therapeutic proposals. So it is important, yes [...]" (Brasília/C4/Physician/04-11)

Thus technical and healing concerns frequently colonize communitarian discourses. The following *discourse graphic* provides us with another example.

Figure 6.6 – Discourse graphic n. 13

(Cape Town/C7/Social scientist/07-11)



This interviewee has been in the committee for four years. With a background in social sciences, she is nowadays a lecturer. During her interview, she clearly manifested a suspicious stance toward pharma companies, a frequent attitude in the *communitarian mentality*. This *discourse graphic* displays all the typical traits of a communitarian discourse: the big variety of communitarian claims; the important role played by pragmatic concerns; the "distortion" of pragmatic claims toward the communicational side, as a result of proto-critique;[117] the *conversation* with bioethical claims; and the *mental colonization* performed by the group of claims TECH13. In addition, there is a considerable score in the group HEAL16, which stresses, precisely, the healing purposes of clinical trials.

It is important to note that as a consequence of *mental colonization*, communitarian discourses are shaken by an astonishing antinomy. On the one hand, holders of the *communitarian mentality* are concerned with national and individual particularities, stressing injustices and sufferings inflicted to vulnerable research subjects. On the other hand, the phenomenon of *mental colonization* proposes claims according to which clinical research is promoting advances whose scope go beyond national and personal differences. As we have seen, some holders of the *communitarian mentality* may experience *mental inversions,*[118] transforming *background* into *foreground knowledge* and vice-versa. Thus, not only *background* and *foreground knowledge* are inversed but there is also a lack of coherence between them. These paradoxes must be contributing to provoke the difficulties faced by some holders of the communitarian approach when asked to express their ideas.[119]

[117] On the issue of proto-critique see section 6.2.1, in this chapter.
[118] See Chapter 5, section 5.3.6.
[119] On the difficulties to express communitarian views, see chapter 4, section 4.2.2.

A common tactics used to deal with these antinomies is to admit the existence of an ideal situation, in which every clinical researcher would be searching exclusively for therapies and medicines. Parallel to this ideal situation, there would be the real world, where other purposes come to corrupt the researchers' goals. The committee member whose interview was the basis for the *discourse graphic* shown above addressed this question in the following manner.

> "*In your opinion, what is the main goal of clinical research?*
> Ideally, it should be better health care, whatever it will make better health care. That is what it should be. Making it possible, you know, without doing any harm.
> *Ideally.*
> Ideally.
> *But in practice... it is not [laughter].*
> Not always [...] Because, you know, there is so much over-research in America, they've moved into Africa and places like that, looking for research populations, and there are those sort of commercial organizations that actually do it for you...
> *The CROs.*
> Is that what they're called?
> *Yeah, CROs.*"

Thus universal healing purposes would be valid in an "ideal" situation, whereas the actual contexts of research reveal inequalities and abuses.[120] This solution may sound weak or incoherent but there seems to be no strong manners to combine communitarian concerns with particularities, on the one hand, and healing concerns with universal health needs, on the other.

Of course, committee members can also mobilize original ideas in order to cope with such antinomies imposed by the phenomenon of *mental colonization.* Even though mentalities constitute ideological patterns, their choice and expression also implies some leeway for creativity and individuality. However, the huge weight acquired by the bioethical/technical/healing ideological structure seems to be reducing the space for personal formulations, as we shall see in the following section.

[120] This solution is not very different from that which is adopted in the *technical mentality,* where an ideal world is imagined where nothing deviates from the search for progress and knowledge.

6.3.6 Lack of personality

The concept of mentality, one of the key concepts in my thesis, comes from German sociologist George Simmel's (1903/1950) theory. One of the main contributions of Simmel's thought was the distinction between objective and subjective culture. Each society is characterized by a set of traditions and material objects, composing the objective culture. In order to adjust and respond to the features of this concrete environment, individuals develop certain types of ideas and philosophies, building up the subjective culture. "The entire life-style of a community depends upon the relationship between the objectified culture and the culture of the subjects" (Simmel, 1900/1997, p. 453).

Still according to Simmel, one of the distinctive traits of modern society is that the overwhelming development of material culture is not accompanied by a correspondent development of subjective culture. "[...] the things that determine and surround our lives, such as tools, means of transport, the products of science, technology and art, are extremely refined. Yet individual culture [...] has not progressed at all to the same extent; indeed, it has even frequently declined" (Simmel, 1900/1997, p. 448).

There are two main factors provoking this apparent paralysis of subjective culture. On the one hand, scientific thought (or "intellect," as Simmel calls it) has proposed fixed cognitive patterns that must be simply followed by individuals, with no need for creative solutions. On the other hand, the monetary economy commensurated almost all sorts of values, reducing the leeway and need for negotiations. As a result, personal and inventive schemes become less and less necessary, and that is why Simmel proposed the idea of "lack of character." Modern society is therefore permeated by an expanding set of material products whereas individuals are asked to use more and more standardized forms of behaviour and thought (Simmel, 1900/1997).

By using these ideas from Simmel, and adjusting them to fit into the theory of communicative action, I am proposing the concept of "lack of personality." In order to understand it, it is important to consider that *mental life* can also be considered as part

of our social environment. Sartre (1960) had already noted that words can be interpreted as something material because, frequently, their meaning and scope can only be recognized and accepted, like objects, by individuals. By the same token, the mentalities described in my thesis have a material dimension, insofar as they are fixed, solidified forms that must be recognized and handled by individuals. Social actors can certainly contribute to transform the mentalities' contents but this transformation cannot be fully carried out without a long and collective process.

Mentalities can also be seen in the light of the idea of technique, in the anthropological sense of this word. According to Mauss (1936, p. 9), technique can be defined as "traditional and efficacious acts." In this sense, mentalities can be said to be ideological techniques, for they are both traditional (they can be passed on from generation to generation) and efficacious (they can be used to build up socially meaningful discourses). Therefore, the objective culture described by Simmel has also an ideological dimension. The consolidation and sophistication of mentalities signalize, at an ideological level, the development of the objective culture.

As Simmel noted, we can therefore say that this objective ideological expansion does not seem to be followed by a parallel development of the subjective culture. On the contrary, there seems to be an over-reliance on *mental* patterns provided by the different mentalities, and the result is the formulation of standardized *discourses* that echo each other. For example, let us consider the following quotes in which three claims appear: one *healing* claim ("clinical research is aimed to generate new medicines"), one *bioethical* claim ("in clinical research there is a risk-benefit ratio"), and one *technical* claim ("research generates advancement").

"[...] the people that get the burden of the research must also get the benefit from the research. So we would often look at... Let's say it is a drug trial where a drug might be found to be of benefit in the end but then what happens to the trial participants that have now benefited from it and the trial is finished? Are you then going to stop the medication or are you going to continue giving it to them? Etcetera etcetera. So the people that take the burden of the research must also be able to participate in the benefits."
(Cape Town/C6/Physician/08-11)

"[...] If you are administering a new medicine, this new medicine should be better, theoretically, than the old one, otherwise there would be no point in incurring the risks of complication or unknown adverse events if you're not benefiting anybody. So all the answers obtained in a clinical study are aimed to benefit somebody, without causing damages.
(São Paulo/C1/Physician/04-11)

"*In your opinion, what is the main goal of clinical research?*
Obviously, it is to improve... it is to improve... I mean, there is always room for improvement in everything we do, not only in clinical research [...] There will always be need for research. Getting better treatments that have less side-effects, that are easier to take.
For the improvement... For the benefit of the patients.
As long as the risk-benefit is better... the risk-benefit is better than what we have [...]."
(Pretoria/C8/Bioscientist/07-11)

"[...] society depends on new techniques, on new procedures, on new medicines, on new cosmetics, on new... on innovations, and people have interests when they make these innovations possible [...] And this is not only bad. This can bring about benefits for society, especially when we talk about new drugs. This brings about benefits. It can produce troubles, it can produce risks, but it leads to many benefits [...] The development of society is realized through research, trough the observation of phenomena. And phenomena happen either naturally or by induction. In human beings, induction is done through chemical products. Such chemical products may be beneficial or not. When they're not beneficial, ethics committees have to evaluate if it is worth approving the risk-benefit ratio [...]."
(São Paulo/C2/Nurse/04-11)

Here, there is no need to ask if the ideas advanced are really important. This question is certainly much more useful for committee members than for sociologists. What is really necessary is to ask whether, with the globalization of clinical trials, there might be such extreme degrees of standardization of discourses. Indeed, with the quotes above, I am giving only four examples of a list that could consume several pages. After reviewing all the quotes speaking of healing trials, risk-benefit ratio and progress in research, we would then be ready to select other widespread claims and spend many more pages with standardized discourses.

We have seen that the *critical mentality* emerges through a *personal formulation* that has to do with biographies and individual ways of processing

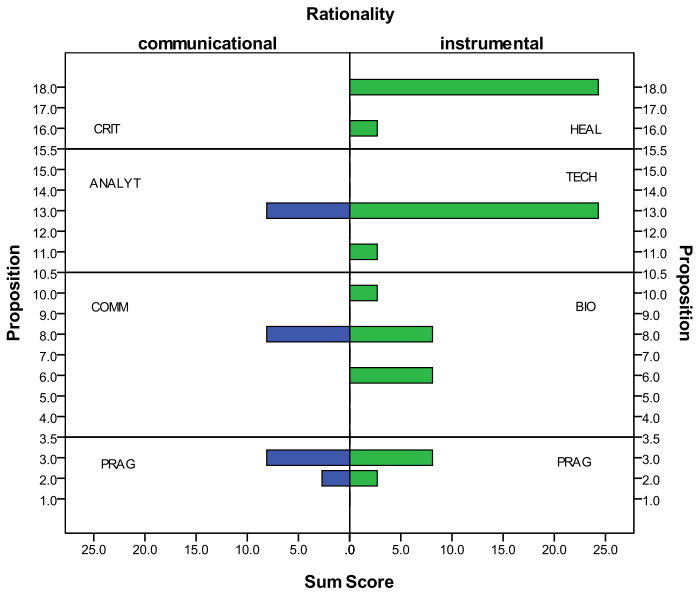
established claims. That is why critical discourses never acquire the force of self-evident ideas. There is certainly some part of critical discourses that ends up plunging into the *background knowledge,* therefore becoming immediate references for holders of the *critical mentality.* However, there is another part of critical discourses that is always ideologically awaken and ready for debate.[121]

For the *healing mentality,* such personal efforts and vacillations are lacking. The contents of healing discourses circulate smoothly in society and are strongly underpinned by social products such as medical associations, statistical disciplines, scientific reports, pieces of news in the media, among others. Thus holders of the healing mentality are supported by powerful ideological references, and their arguments lie on very strong social scaffolds. For some individuals, "standing on the shoulders of giants" represents an opportunity to see further away; for other individuals, however, it simply means that protection and success has been obtained, and that there is no need to aspire to go any higher. As a result, people voicing strong healing discourses mobilize vague arguments, circulating between the bioethical, technical and healing approaches without much coherence. The following *discourse graphic* gives us an example.

[121] As we can see in Figure 3.1 (page 71), only part of the *critical mentality* is inserted into the *background knowledge.*

Figure 6.7 – Discourse graphic n. 19

(São Paulo/C2/Nurse/04-11)



By the time of our interview, this nurse had been in the committee for only a couple of months. Several times, she stressed her doubts in terms of scientific procedures and research methodologies. Even though she receives only qualitative, "low-risk" projects, she appears to be extremely cautious in her reviews, being somehow afraid of making mistakes. In my observations of meetings, it was interesting to see that she interfered in discussions by the single means of asking questions about methodologies and concepts. In one particular meeting, in a moment when the committee discussed one project she had reviewed, her questioning attitude was reinforced, for in addition to asking about methods, she had many questions about her own way of framing the project.

Two aspects call the attention in the graphic above. First, the discourse is massively dominated by two claims: TECH13, which stresses the competence of specialists to analyze research proposals; and HEAL18, which foregrounds the humanistic and dynamic features of clinical research. In the following quote, she speaks of the evolution undergone by clinical research and ethics committees.

"Maybe in the future... I don't know the evolution of other committees, but things are rethought, you know. Are these procedures the best ones? Are they appropriate? I think there is... And there is a dynamics. I think the committee is a dynamic thing.

That is, in ten year's time, it will be a different thing.

It may be. I think it tends to advance, you know, as in the whole scientific world. It is not a paralyzed, still thing. I think so.

And do you think that because it is scientific... Even though it is scientific, can it get close to the patients or do you think it remains far away from patients and closer to this scientific world?

It depends very much on how this is presented to the patient, to those who are going to participate in research [...] So when you explain, when you elucidate, you somehow make the subject participate in your research in a different way.

So it all depends on the explanation.

On the explanation. I think this is important. What is going to happen. I think everything must be *very* well explained to the person, without implicit things. Each phrase. The reasons. I think the subjects have this right because they're going to make it possible for the researcher to discover something, to claim something, you know, depending on the kind of research."

During this whole interview, the conversation was kept at this highly general level and the interviewee did not refereed to examples or more precise concepts. This is exactly the second point to be stressed in the previous *discourse graphic:* there are many gaps between claims, an unusual event if we compare it to other graphics. We went on jumping from the idea of the specialists' expertise (claim TECH13) to the idea of full informed consent (BIO8), and from this topic to the broad purposes of trials (HEAL18). Although this discursive strategy may be imposed by her little experience as a committee member, this fact does not seem to be decisive, because another interviewee, who voiced a strong analytical/critical discourse, had been in another committee for only a couple of months as well.[122] Therefore, it seems that the main aspect to be considered here is the internal discursive structure of the healing mentality, which reduces claims to a small and unspecific set of ideas that end up being framed as self-evident.

[122] This *discourse graphic* can be seen on Chapter 5, Figure 6.4.

The concept of *lack of personality,* then, points to this high level of standardization in people's discourses. In different cities and countries, claims seem to be echoing each other, with very little interference of an actual *personal formulation*. Whereas the *critical mentality* presupposes an individual effort to combine personal experiences with lessons provided by the analytical approach, people holding the *healing mentality* seem to be satisfied with only marshalling ready-made claims and repeating arguments springing from ideologically powerful social institutions and actors.

In this way, it is worth asking if people are really voicing what we can call opinions. The formulation of opinions depends on lengthy reflections, through which events are seen in the light of personal formulations. According to Arendt (1963, p. 272): "Opinions are formed in a process of open discussion and public debate, and where no opportunity for the forming of opinions exists, there may be moods – moods of the masses and moods of individuals, the latter no less fickle and unreliable than the former – but no opinion." Therefore, the highly standardized discourses voiced by many of my interviewees would be expressing not so much opinions, but moods suggested by massifying processes.

This aspect has not only philosophical and personal consequences but political ones as well. The global system of clinical trials is strongly supported by the ethics committee model. As some authors noted (Kohlen, 2009, Petryna, 2006), the proliferation of ethics committees was in tune with the trials companies' needs. Since the 1990s, the "impetus for ethics committees" has been derived not only from governments but also "[...] from the self-regulation of the health care industry: mainly in connection with 'quality assurance'" (Kohlen, 2009, p. 85). Parallel to my PhD study, I conducted another research project focusing on the organization of global trials in the UK, Spain, France, Brazil and South Africa.[123] It was possible to see that CROs and physician-investigators hasten to point out that everything is being approved by ethics committees, especially when they speak of controversial aspects of trials (such as placebos or payments made in clinical studies).

A political dilemma emerges. On the one hand, ethics committees are said to be the gatekeepers of morality and fairness in clinical trials, assessing the industry's

[123] Further information about this parallel study is provided in Chapter 2.

actions. On the other hand, committee members seem to hold precarious ideological tools to assess the worth of studies, frequently limiting themselves to the repetition of claims diffused precisely by the industry. As a result, the ethics committee model threatens to turn into mere discursive justification, rather than being a really decisive part of the global research system.

The healing mentality, when focusing on ethics committees, brings about the idea that committees would be carrying out a useful service. However, we are not dealing with a service in the same sense that the *communitarian mentality* describes it, that is, we are not dealing with a service that would benefit particular groups and institutions. The *healing mentality* frames committees as providers of a humanistic work, as we shall see in the next section.

6.3.7 Healing committees

The *healing* idea that clinical trials aim to generate medicines that can eventually prove beneficial for humankind has direct connections with the *technical* idea that knowledge gleaned from trials is universally valid. By combining these two claims, one eventually proposes a very ambitious description of clinical research. As we have seen, such descriptions are often formulated by pharma companies and CROs. Such discourses have been largely diffused, as well as assimilated by a vast range of social actors. For example, Fisher found out that in research settings in the United States, many study coordinators come to internalize a "big picture" of trials. "From coordinators' own perspective, they are always already engaged in what they see as the 'big picture' – the advancement of medicine for the benefit of humanity" (Fisher, 2009, p. 87).

Even though this type of view was not manifested very frequently in my fieldwork, I came across some discourses in which ethics committees were covered with healing hues. In this way, committee members would be participating in a huge, global effort to fight diseases.

"*Today, what is your main motivation to continue to work in the committee?*
[...] I would say it is to improve my knowledge-basis even further, for me to know what the breakthroughs in science are. Okay? And for me to actually... It is actually a feeling of euphoria when I hear that these new methods of treating debilitating conditions... You know? It is almost like... It is... It is like a relief for the patient. If the patient was limited to be walking around in callipers or wheelchair all the time, if they take this medication, they'll maybe be able to walk a little bit or be more flexible or be more mobile and things like that. So every time I go... I go with this enthusiasm that I'm hearing something new today... You know. So that is the incentive, so to say [...]."
(Cape Town/C7/Nurse/07-11)

The underlying assumption is that clinical research forms a global scientific community, involving researchers, statisticians, companies, research subjects... and committee members, everybody joining this universal battle against illnesses. At times, some interviewees sounded somewhat disturbed by this broad vein of their own discourses, like in the following example.

"*In your opinion, what is the main goal of clinical research?*
[Pause.] I think... [Long pause.] I think that the main goal, theoretically, is to understand how a medicine or a therapeutic activity can (any type of therapeutic activity) can benefit (with quotation marks), or to understand the effects provoked by this activity in human beings. I think that, theoretically, this would be the goal. To understand how a therapeutic activity x, y, z (no matter how, whether a medicine is used or there are other things) can influence, can act in human beings. I think this would be.... But for that... This is so... This is actually so utopian and so distant, you know, in terms of research, and especially here in Brazil, where you have an idea for something today and it takes maybe fifteen years for you to have a final answer, you know. And this will never arrive: 'the end.' It is always partial [...]."
(São Paulo/C3/Bioscientist/04-11)

Indeed, by listening to some technical/healing discourses, one might have the impression of "utopian" or "distant" notions, as this interviewee put it. The same feeling emerges when one advances a healing approach to ethics committees.

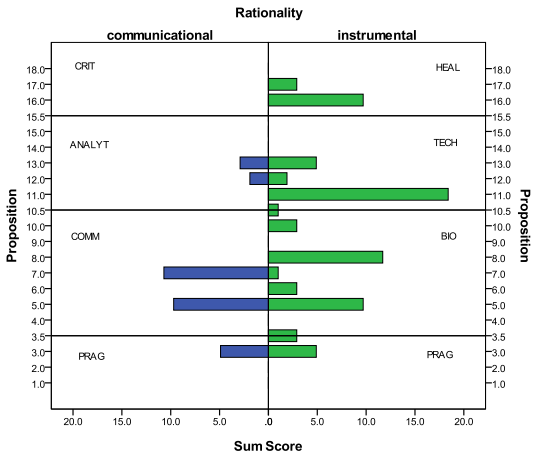
"*Do you think an ethics committee is somehow related to teaching activities?*

I think it fosters knowledge, it fosters research. The majority of our studies here are not linked to big amounts of money... You participated in one meeting, you saw it. It is much more related to the studies of our post-graduate students, our junior researchers, our research assistants [...] Sometimes we have a huge multidisciplinary study with... That is true, we have an excellent head of department here and he sometimes come up with a very big study, and that is also good. We've been working for eight years in a study on papiloma virus, the HPV virus [...] If I forget my humble position as a humble lecturer with a couple of students for a while, and if I think of the macro-level, as a health worker, participating in the development of a vaccine that is so beneficial for the population... That is perhaps a bit idealistic from me, but that is how I am. So there is no other way to define me [*laughter*], do you understand?"

(São Paulo/C2/Physician/04-11)

It is important to say that this physician was not engaged in the mentioned HPV study. Actually, he does not conduct clinical trials. Therefore, when he says "We've been working for eight years in a study," he is assuming that, somehow, the whole hospital, and certainly the ethics committee as well, are involved in this research effort. As the quote shows, this grand assumption is quickly tempered and interpreted as "idealistic." The following discourse graphic derives from the interview with this physician.

Figure 6.8 – Discourse graphic n.1



The interviewee has worked in the hospital, as well as in the committee, for thirteen years. As a consequence of this large experience, he has developed, so to say, a feeling of solidarity towards the hospital and the committee, institutions where he feels at home. His discourse can be defined as technical/healing, being strongly supported by bioethical claims. In this type of discourse, pragmatic claims tend to be even less important than they are here. As the graphic shows, his discourse

is dominated by the group of claims TECH11, which stresses the relevance of trials for the generation of new knowledge, but there is an important role being played by HEAL16, which foregrounds the therapeutic purposes of trials.

When speaking of ethics committees, holders of the *communitarian mentality* can also experience the effects of *mental colonization.* As a result, committees end up being described, at the same time, as institutions imparting a relevant service to a country or region, and institutions making it possible to investigate and generate new therapies. The following quote has been broken in different parts.

Question
?
Communitarian
Communitarian/Healing
Healing

"*Do you think the [committee] members should get paid?*
No, I don't think so.
Why?
I think that... That is my personal view. I think it doesn't take away from me any...
Let's say I consider it as a relevant service. We have in our Constitution, as examples of citizenry, the possibility of giving our contribution with relevant services, almost like non-profit organizations. And I think in the committee people are...
the time people spend there is to do a service devoted to other people, you know,
to other people's well-being or therapy [...]."
(Porto Alegre/C5/Lawyer/05-11)

Focusing on two research settings in the United States, Timmermans (2011) verified that negative results can be frustrating for the research staff, as these people are motivated by the idea of being "at the forefront of testing a drug." Thus professionals involved in a trial (such as nurses, data analysts, study coordinators, and the principal investigators themselves) may develop "a commitment to both the therapeutic and the expected scientific goal of the trial," as well as "the expectation of making a difference in people's lives" (Timmermans, 2011, p. 558). In Fisher's (2009, p. 202) study, it was also verified that the research staff often hopes to see "the marketing of experimental drugs on which they worked."

Ethics committee members are not immune to such wishes. Working on a voluntary basis, with no remuneration and little institutional recognition, they may accept a healing approach to committees in order to find some type of motivation.

One might suppose that this motivation, as well as other assumptions that prevail in the healing mentality, are more frequent for physicians and nurses, who are the "professional healers" of society. However, it was already shown that healing claims are largely diffused, being independent from professional backgrounds. This is one of the issues explored in the next section.

6.3.8 Political implications of the healing mentality

In my fieldwork, healing claims were mobilized not only by committee members engaged in healing activities (physicians and nurses) but proved to be very widespread. By performing statistical tests, I could not verify significant differences in terms of professional background and experience in the committee. Strong correlations with other mentalities were not detected either. Thus, healing claims demonstrate a characteristic that is typical to the *background knowledge:* they have become natural and obvious enough to acquire large acceptation.

Once again, the consolidation of a mentality can have important social consequences. As soon as healing claims become largely recognized, some actors can struggle for the right to become research subjects. In the United States, for instance, some groups have campaigned for the inclusion of minorities in trials, claiming that these groups should also be taken into account in medical investigation (Epstein, 2007). In this same country, some people try to join clinical studies in order to solve pressing health problems (Fisher, 2009). Ethics committee members are quite aware that at some point, clinical trials may be framed as a therapeutic scapegoat.

> "*When you're reviewing a protocol, do you somehow think about the people who will take part in the study?*
> Oh, I think this is natural, you know. You have to think about them. Even though you're analyzing a document, that involves, in fact, patients' lives, you know. And when we're analyzing an oncologic protocol, for instance, we imagine a complete hopeless patient trying to take part in a study, you know, to have a last hope to survive [...]."
> (Porto Alegre/C5/Physician/05-11)

In countries such as South Africa and Brazil, where large populations still face difficulties to access health care services, trial participation can be framed as a therapeutic alternative. One interviewee, for instance, complained that many people in South Africa, by considering the health hardships of the country, have become excessively permissive towards global trials, considering them as obviously necessary.

> "*Maybe committee members can also share this view about clinical trials. Do you think so?*
>
> I think there are certainly some people on the committee that share this view, whereas some people are quite concerned. [Pause.] But these are not easy arguments because what I just stated is also factually true: this is a needy country; lots of patients do not get adequate care for their conditions; there is not enough funding for medical research in this country; and pharmaceutical trials fulfil and have a role in that regard because they fund medical doctors and it, in the end, you know, benefits this country that these doctors are here; they provide clinical care to patients that they wouldn't otherwise get; and they are let with funding from these trials; it actually does fund medical research [...] I think it is a very difficult situation because... It really isn't black and white. Not having these trials or preventing these trials that are happening here, that might cost the patients more than these trials actually happening."
>
> (Cape Town/C7/Bioethicist/08-11)

Pharma companies can use this complex context strategically, as we can exemplify with a story from Brazil. The Brazilian government has an internationally renowned programme that provides free anti-retroviral drugs to every citizen infected with HIV. Over the last years, the maintenance of the programme has not been a simple matter. It is known that in 2003, 63% of the Brazilian Ministry of Health's budget was spent on only three anti-retroviral medicines produced by Abbot, Roche and Merck (Bicudo, 2006). This proportion has been reduced by internalizing the production of some medicines for HIV-Aids. However, companies, having realized that the state is a good buyer, have tried to replace anti-retrovirals with other sorts of medicines.

On this point, the story told by Petryna (2009) is illustrative. Over the last years, some pharma and biotech companies have tried to enlarge the list of medicines

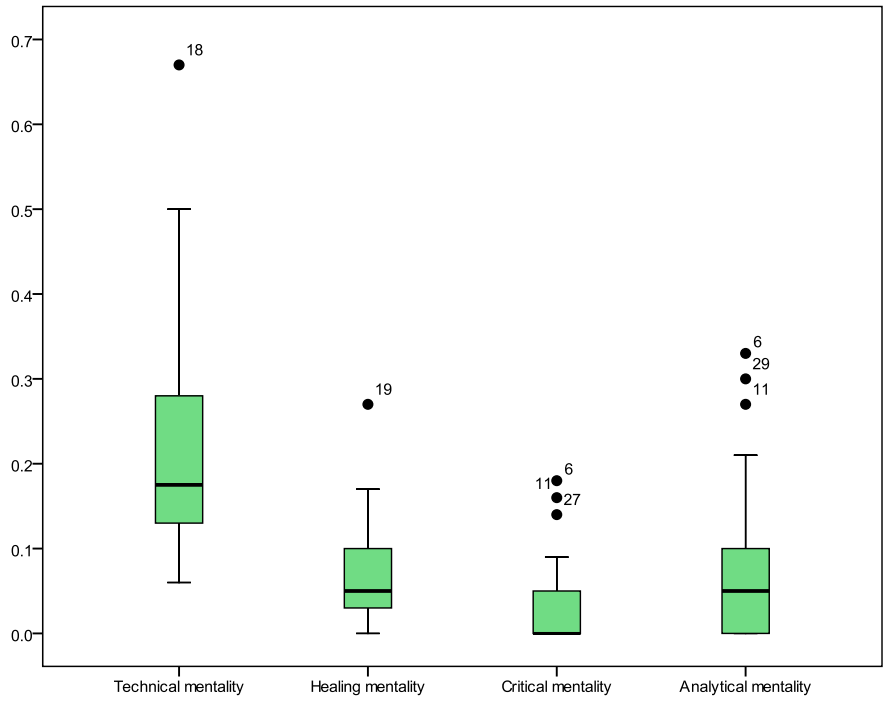
bought by the Brazilian state and provided for free to its citizens. The strategy consists in funding advocacy groups, lawyers or individual patients so that these actors open lawsuits against the Brazilian state, asking for the inclusion of certain medicines into the free-provision programme. As a consequence: “The number of legal suits filed by patients against municipal and state health departments has skyrocketed throughout Brazil in the last decade” (Petryna, 2009, p. 151). Admitting that the search for health is as a universal and natural right, one forces a political situation in which these rights should be guaranteed by the national state. Insofar as the healing mentality has attributed healing purposes to every kind of social actor (healing physicians, healing companies, healing scientists, healing ethics committees, and so on), the state can finally be asked to assume healing functions as well. As healing capacities are seen in the framework of globalized pharmaceutical studies and productions, the healing state should necessarily be the state-provider-of-medicines.

Here, the issue of *lack of personality* plays a decisive role. The fight for health, understood as the fight for the individuals’ physical well-being, has become so self-evident that there seems to be no leeway for discordant voices. As soon as one wishes to contest the pathways through which medicine and research have been taken, it is necessary to counter the strong rock of healing claims, which have acquired the ideological force of uncontested background assumptions. On the one hand, the formation of *opinions* about global trials and medicines depend on lengthy, careful reflections. On the other hand, the standardization of discourses, as well as the advanced triumph of the healing mentality, tends to reduce the leeway for alternative views and inclusive social debates.

6.4 Conclusion

The following boxplots compare the *technical, healing, critical* and *analytical mentalities.*

Figure 6.9 – Discourse boxplots: technical, healing, critical and analytical mentalities



Statistically speaking, the *technical mentality* is significantly superior to all the other three approaches.[124] There is no significant difference between the *healing* and *critical mentality.* However, there is an interesting discrepancy when we compare them to the *analytical mentality.* While there is no significant difference between the healing and analytical approaches (p=0.92), I verified a significant difference between the critical and the analytical approaches (p less than 0.0005).

Thus, there are two conclusions to be drawn. Firstly, the healing and critical approaches can really be described as extreme views, for they are significantly inferior to the majority of other mentalities. Secondly, if we consider the *healing* and *critical mentalities* as extreme views, the critical approach seems to be particularly extreme, for it is significantly inferior even when compared to the rare analytical approach.

The widespread occurrence of certain healing claims can be explained by the following factors:

[124] The tests I used here were: Friedman's test (K related samples), to compare all *mentalities;* and Wilcoxon's test (2 related samples), to compare *mentalities* individually.

- Healing claims are anchored in the basic assumption that every-body, by possessing a human body, can at some point engage in a struggle against disease
- The globalization of research projects, with partnerships involving not only companies but also universities and state agencies, suggests the idea that illnesses are being fought through humanitarian efforts
- The assumption that committee members are somehow contributing to generate new, useful medicines can be personally rewarding, especially because committee members generally work with no economic remuneration and little institutional recognition
- Healing claims are in tune with the powerful *technical mentality*, which has obtained a large political dominance, be it by means of direct influences (upon the *bioethical mentality*) or through indirect influences (upon the *communitarian mentality*)

On the other hand, critical claims continue to be ideologically marginal. They are not only rare (representing small proportions in most interviewees' discourses) but also particularly extreme (being significantly inferior to all approaches but the healing one). Their precarious diffusion can be explained by the following circumstances.

- The poor diffusion of analytical claims (whose aspects were addressed in the previous chapter) provokes a timid development of critical claims, for the *analytical mentality* is a condition for the emergence of the *critical mentality*
- Homogeneizing trends of the mass society leads most people to prefer "ideological behaviour" to engaging in the costly *personal formulation* of a critical view
- For most committee members, problems of clinical trials are framed as obstacles to be transposed by means of scientific, social or methodological corrections. Therefore, there is little leeway for the idea that these problems are rather *crises,* that is, flaws that are necessary to the system of clinical experimentation

- The critical mentality may sound politically costly, insofar as it concludes that reforming clinical trials would require drastic and radical measures, involving the transformation of a complex system

Differently from the *communitarian* and *analytical mentalities,* the critical approach brings about some clues in terms of practical measures and actions to be undertaken. Nevertheless, many actors may look at these proposals as too unlikely to succeed. Thus, the internal discursive structure of the critical mentality impairs its social dissemination.

However, if we come back to the boxplots presented in Figure 6.9 above, it is possible to see that, for both the *analytical* and *critical mentalities*, there are four interviewees (represented as dots above the actual boxplots) who voiced atypically high proportions of analytical and critical claims. These are rare interviewees voicing rare discourses. In statistical boxplots, they are simply numbers (in this case, numbers 6, 11, 27 and 29). However, I remember these persons very well. I recall the feeling of surprise and bewilderment experienced at the end of these interviews. This is certainly the feeling that one experiences when facing the new and different after having become used to the standard.

It is somewhat strange to verify that analytical and critical stances are very rare among ethics committee members who are supposed to analyze and criticize. However, it is also interesting to see that analytical and critical instances are still possible, albeit rare, being supported not only by individual preferences but also by long-lasting social processes.

Chapter 7 – Conclusion

After having described all the mentalities identified in my research, this conclusion recalls and reinforces the main ideas advanced previously. Parallel to this, some ideas are presented whose scope go beyond the specific study of ethics committees and clinical trials. We begin these tasks by reviewing the main characteristics of mentalities, as well as pointing to the advantages of this communicative approach for sociological explanation. Subsequently, we draw attention to the growing number of heavy responsibilities that ethics committees have assumed. After discussing the political aspects of my interpretation, I focus on the nature of a communicative approach to ethics committees. Finally, the globalization of ideologies is addressed.

7.1 Mentalities and sociological interpretation

Even though my PhD research process involved careful literature reviews and some observations, the analysis of committee members' discourses clearly constitutes the most central aspect of it. Todorov's (1984) distinction must be remembered: in my study, I was not concerned with "truth" (the accurate expression of one's internal universe) but with "verisimilitude" (the expression of discourses endowed with cultural meaning). In this way, there is no need to ask whether my interviewees voiced real points of view or simply tried to construct embellished discourses. Even if social actors wish to deceive by voicing dishonest claims, these latter must be somehow referred to broad, socially available, historically constructed ideological structures. My study draws the attention to these social structures, instead of focusing on psychological characteristics.

In addition to my central qualitative interpretation, ancillary statistical tools were used to test differences and display discourses graphically. These statistical operations might be considered as too flexible or heterodox methods, going too far away from conventional ways in which sociology has used statistical tools. However,

considering the objectives established at the beginning of our trajectory, it seems to me that very conservative research pathways could not lead to interesting outcomes. In addition, it is important to consider that for any kind of discourse analysis, a certain amount of discretion and choice is required. According to Denzin (1998, p. 313): “In the social sciences there is only interpretation. Nothing speaks for itself.” As Becker (1996, "The actors point of view") argues:

> “[...] all social scientists, implicitly or explicitly, attribute a point of view and interpretations to the people whose actions we analyze. That is, we always describe how they interpret the events they participate in, so the only question is not whether we should, but how accurately we do it.”

I tried to guarantee my interpretative accuracy by describing mentalities without being judgmental towards them. However, as claimed in Chapter 5, this target cannot be fully reached. Insofar as every discourse is situated, or embedded in the “lifeworld” as Habermas (1996) would put it, and insofar as my text is also a discourse, it is not possible to voice a neutral interpretation, which would be separated from all mentalities. As it seems to me, my interpretation is proposed from an *analytical* point of view, and my description of mentalities is influenced by this circumstance. However, the worth and coherence of my analysis is guaranteed by an effort to comprehend the nature and sources of all mentalities.

This point needs to be reinforced. When I claim that my point of view is analytical, I am not suggesting that this is the best approach. Sociologically speaking, there is no need to depict one particular mentality as the “cleverest” or “most appropriate.” Whenever social actors embrace a certain mentality, they draw an ideological field in which the definition and scope of “cleverness” and “appropriateness” assume new forms. In this sense, there is a correspondence between the concept of mentality and the idea of “styles of reasoning,” as proposed by Hacking (1990, p. 7):

> “[…] styles of reasoning are curiously self-authenticating. A proposition can be assessed as true-or-false only when there is some style of reasoning and investigation that helps determine its truth value. What the proposition means

> depends upon the ways in which we might settle its truth. That innocent observation verges nervously on circularity. We cannot justify the style as the way best to discover the truth of the proposition, because the sense of the proposition itself depends upon the style of reasoning by which its truth is settled. A style of thinking, it seems, cannot be straightforwardly wrong, once it has achieved a status by which it fixes the sense of what it investigates. Such thoughts call in question the idea of an independent world-given criterion of truth."

Once one individual adopts a certain mentality, he or she is immediately defining relevant questions, as well as possible answers and explanations. Thus a sociological interpretation must not try to indicate what is the best approach, but try to understand how different approaches *converse,* reinforcing or opposing each other. This does not mean that everything is possible and laudable in mental life. It only means that truths and mystifications are products of social debates and relations, instead of being *a priori,* evident ideas to be defined at the outset of our analyses.

My interpretation diverges from those in which linguistic aspects tend to acquire a certain explicative autonomy. In Latour, for example, claims are said to be valid as soon as they are trusted and supported by other claims. "One sentence can be made a fact or a fiction, depending on the ways in which it is inserted into other sentences. *In itself, one sentence is neither fact nor fiction; it becomes one of these things later, thanks to other sentences"* (Latour, 2000, p. 45). In the theory of communicative action (Habermas, 1981/1987, Habermas, 1996), which underpins my study, claims do not have this sort of autonomy. One bioethical claim (like "the research subjects' autonomy must be protected") will necessarily die out if it is not underpinned by the actual organization of committees and regulatory agencies, the bioethical vein that is often assumed by guidelines on clinical trials, the operations of bioethical associations, among other underpinnings. Thus communicative actions are not referred to themselves; rather, they are always referred to concrete processes happening in particular countries and places. By means of this theoretical stance, claims are "brought down from transcendental heaven to the earth of the lifeworld" (Habermas, 1996, p. 18-19).

The flexibility of communicative processes, as well as the communicative liberty of social actors, needs to be carefully described as soon as we consider, for instance, the presence of *background knowledge* (which was described as *pragmatic mentality* in the framework of my study). Certain basic assumptions about clinical trials have come to be widely diffused, imposing themselves as taken-for-granted ideas, not because they are supported by previous claims, but because the global economy of trials has taken a certain shape. One can therefore assume that the contents of *background knowledge* must change as soon as this economic organization changes.

The point to be stressed here is that *rationalities* and *mentalities* are subjected to geographical and historical processes. As for their geographical dimension, *mentalities* can be described with reference to the mechanism pointed to by Santos (2000): global processes bring about certain possibilities, which are realized in distinct ways by different countries. Thus in each country the effects of global trials acquire particular features and, consequently, *mentalities* are also differently constituted. For example, as explained in Chapter 4, the *communitarian mentality,* in South Africa, is shaped by the Aids epidemic, whereas Brazilian holders of this *mentality* are frequently concerned with regional inequalities.

The historical dimension of mentalities is equally decisive. As we have seen, each mentality is the product of a process through which claims are consolidated and disseminated. To be sure, all mentalities derive from the same historical processes. However, each mentality deals with historical events in its own fashion. For instance, past scandals in clinical trials are seen, by the *communitarian mentality*, as proofs that uncertainties are always present in clinical research; whereas the *bioethical mentality* frames these scandals as evidence that bioethical principles have been overlooked and must be mandated by regulations more strongly.

The globalization of trials itself is given a different meaning by the different mentalities, as summarized below.

BACKGROUND KNOWLEDGE

- In the *pragmatic mentality*, global trials are said to be motivated by financial and economic interests held by companies and investigators

INSTRUMENTAL RATIONALITY

- In the *bioethical mentality*, global trials are thought of as activities triggering ethical problems whose solution requires the mobilization of ethical calculations
- In the *technical mentality*, they are said to be the product of scientific and statistical imperatives
- The *healing mentality* understands them as a natural stage in the history of the human fight against diseases

COMMUNICATIVE RATIONALITY

- In the *communitarian mentality*, global trials are framed as opportunistic enterprises threatening the particularities of vulnerable countries and populations
- The *analytical mentality* frames them as activities through which companies tinker with scientific methods in order to reach financial goals
- In the *critical mentality*, they are thought of as activities fraught with fundamental problems whose solution asks for radical changes in the global research scenario

Mentalities are, thus, lenses through which social processes are observed. Even though individuals do have some space for the formulation of personal, original ideas, the consolidation of mentalities, as well as the fact that they can be identified in different cities and countries, indicates that in mental life, there is also much leeway for imposition, *colonization* and standardization. The nature of mentalities reminds us of the "series of acts" described by Mauss (1936, p. 21): "[...] one of the reasons why these series can be easily constructed in individuals is precisely that they are constructed by and for social authority." In the same way, mentalities are, as it were, ideological boxes limiting the individuals' scope of choice.

In communicative action theory, the concept of *background knowledge* points to rigid aspects of mental life. It was shown that, to a great extent, the ethics committee members' work is informed by background assumptions. The pragmatic approach is widely diffused. The bioethical and communitarian approaches (which are

embraced by a large number of my interviewees) maintain important direct connections with the *background knowledge.* The healing approach has been transformed into a background approach, thanks to the *industrial formulation* focused on in Chapter 6*.* Finally, the critical approach itself is partly embedded in the *background knowledge.* Therefore, there are only two mentalities (*technical* and *analytical*) that are fully related to the *foreground knowledge*, the realm of debates and contestable claims*.* If we consider the small number of interviewees who voiced analytical discourses, then it is clear that, for the most part, committee members seem to be favouring immediate, taken-for-granted ideas (*background knowledge*).[125] As a consequence, standardized discourses end up prevailing, and there seems to be little leeway for the formulation of actual *opinions.*

On the one hand, committee members seem to maintain timid contacts with the *foreground knowledge*. On the other hand, by discussing research proposals in regular meetings, they are supposed to deal with pressing questions brought about by global trials. We further explore this dilemma in the following section.

7.2 COMMITTEE MEMBERS AND THEIR SUPERHUMAN TASKS

As explained in the Introduction, the globalization of the ethics committee model derived not only from local efforts but was also fostered by the United States' regulatory agencies and the trials companies themselves (Epstein, 2007, Kohlen, 2009, Petryna, 2009, Shah, 2006). This is how Petryna (2009, p. 38) summarized the logic of the process: "Let regulators name the responsible local parties (in some cases, this would mean first creating such oversight bodies) and surely those parties can gather information and make the right decisions; surely they can prevent inappropriate research."

In some countries, the creation of an ethics review system has not been straightforward. For instance, Shah (2006, p. 135) referred to a 2001 report published by the National Bioethics Advisory Commission (NBAC), which advises the US National Institutes of Health:

[125] Analytical discourses are equally rare in the social science literature on clinical trials.

> "NBAC researchers had found that in Morocco […] there were no ethical review committees, and 'the Ministry of Health does not feel that it is necessary.' Turkish officials had 'serious reservations' about setting up ethics review committees. Researchers in Haiti said there had been no ethics committees in their country until 1999. Researchers in Uganda revealed that 'the notion of an unbiased, uninvested review committee' was still 'quite new' to the country."

For many interpreters, including Shah herself, this evidence suggests that ethics committees should be created and reinforced wherever they are lacking. It seems that apart from Kohlen (2009), no one has asked whether the ethics committee model, as it was formulated in the United States, is really worth being globalized and taken as the "gold standard" of ethics review. This question is important because, as explained throughout my thesis, this current model fosters the consolidation of a bioethical/technical approach, which, in its turn, brings about a particular political discourse.

National settings that, in the 1990s, were suddenly engulfed in the storm of global trials (including South Africa and Brazil) had to constitute their ethics committees system as rapidly and carefully as they could. As a result, many countries ended up constructing somewhat fragile ethics systems. For example, Nyika and collaborators (2009, p. 192) studied 31 African ethics committees in 2007 and concluded: "Whereas the volume of trials being conducted in Africa is increasing, 92% of the surveyed committees reported that they are inadequately trained to properly review and monitor trials."

Indeed, training is a decisive issue. Apart from courses and seminars on ethical aspects, frequently attended by committee members, the South African and Brazilian committees I studied do not offer other sorts of training on clinical trials, in order to explore technical, economic and methodological aspects of research projects. In addition to these knowledge gaps, there seem to be ideological gaps, as most members tend to rely on standardized discourses, deeply informed by background assumptions. Ethics committees, which are supposed to analyze, discuss and debate protocols, seem to be limited to procedural tasks and standardized discourses. Committee meetings (and I observed 11 of them during my fieldwork) tend to become simple formalities, while committee members (and especially those who hold

analytical and critical approaches) are paralyzed by bureaucratic ways to assess research proposals, in addition to being suffocated by busy meetings in which a growing number of projects must be discussed in a couple of hours.

It is crucial to stress this issue because over the last years, ethics committee members have been given superhuman tasks. On the one hand, as claimed in Chapter 4, committees' decisions are sometimes seen as an early form of justice. On the other hand, after many measures taken to flexibilize international guidelines on clinical research, ethics committees were made responsible for taking decisions on thorny issues such as the use of placebos in trials (Petryna, 2006, Dirceu Greco in Oselka and Oliveira, 2007, Petryna, 2009, Shah, 2006).[126]

From the viewpoint of the trials industry, this state of things looks rather convenient. In order to fulfil their tasks, ethics committees may struggle in the middle of knowledge, infrastructural or ideological limitations. However, the final approval they issue will anyway provide companies with the ethical sanction they are looking for. "The company is ostensibly safe from liability concerns if the local institutional review board approves the protocol and patients sign the informed consent forms […]" (Petryna, 2009, p. 105). In this system, defined by Petryna (2009, p. 67) as "privatized and highly individualized," both research subjects and ethics committees end up being framed in the same way: as autonomous, rational decision-makers. When it comes to ethics committees, this definition is not extremely unrealistic, insofar as committees have been forced to embrace a bioethical/technical/healing approach that proposes commensurable, general principles and procedures, and which, on many occasions, is in tune with the trials companies' expectations. Therefore, in addition to being concerned with "regulatory capture" , analysts and policymakers have reasons for being concerned with *ideological capture*, defined (in Chapter 5) as the process through which the reviewers of research proposals begin to share hopes, expectations and theoretical frameworks with researchers and companies that submit proposals.

This is perhaps why, over the last years, committees have been obliged to adopt a rather permissive stance; hence, the idea of justification, frequently invoked

[126] When it comes to advisory scientific committees, expectations can be even higher. This is how Salter describes this situation: "By providing a framework within which often emotive cultural divisions can be addressed, bioethics committees enable disputes to be defined in ways capable of producing policy outcomes." See SALTER, B. 2007. The global politics of human embryonic stem cell science. *Global governance*, 13**,** 277-298.

by committee members. Most members acknowledge that some issues of global trials are quite controversial, but many seem to get easily satisfied as soon as investigators justify their procedures. One instructive example is the issue of post-trial access. Shah (2006, p. 136) described the situation in the following manner: "Researchers should make 'reasonable, good faith efforts' to provide study drugs to subjects after trials' end, but if not [...], they should simply present their justifications to their ethics committees." Here, justification turns into a password with which dire dilemmas seem to be quickly circumvented.

> "[...] these are the sort of things we look at. Is there going to be post-trial access? Not only for HIV; for cancer, for some of these rare diseases, for patients with direct benefit. We think we should continue until the drug is registered or until it can be accessed from the public sector [...]
> *Hm. But it is difficult to make sure that there will be post-trial access, isn't it?*
> [Immediate reply.] No, we recommend, and they must justify why they're not giving it [...]."
> (Pretoria/C8/Bioscientist/07-11)

Confronted by multinational corporations, which have established high-skilled offices with the ability to scientifically "justify" many sorts of procedures, ethics committees may become a docile part of a global ethical ceremony. Arguably, this is why, as Chamblis (1996) argued, committees are frequently prone to focus on less controversial, highly standardized issues of clinical research. By the same token, Bosk and Frader (1998, p. 113 note 10) argued that committees "[...] can be nothing more than an attempt to preserve professional power by internalizing a critique and thereby disarming it." In this sense, committees are repeating the operations described by Edelman (1992): symbols of compliance to law become more important than an actual willingness or capacity to comply. In a politically harmful way, committees can thus mediate between the global market and the legal life of countries. They would be state-law-laden (whether this happens at a concrete or purely symbolic level) so that the industry can be market-standard-laden.

In spite of all these processes, committees have not become the *instrumental rationality's* free zone. There is still some space for ideological controversies and debates, as explained in the following section.

7.3 ETHICS COMMITTEES, COMMUNICATION, AND POLITICS

Identifying the *communicative rationality* in committee members' discourses was an important finding of my study. This means that some members have an approach that is not only different from, but can also be opposite to, the hegemonic bioethical/technical discourse. To be sure, the *analytical* and *critical mentalities* seem to be quite rare among committee members. However, in the framework of a mass society, rarity seems to be a necessary characteristic of divergent thoughts and reflected *opinions.*

The point to be stressed is that committees participate in broad communicational processes. Seen from a communicative standpoint, they are spaces where discourses are voiced, and such discourses are shaped not only by global issues but also by local aspects. For instance, some committee members may be holders of communitarian concerns whose contents are contextual phenomena such as the possibility to pay 150 Rand to research subjects in South Africa, the high levels of illiteracy in a certain Brazilian hospital or the high incidence of tuberculosis in South Africa. Each topic can only be identified because there are *mentalities* available in order to grasp and interpret them. In this way, committees are not favouring the interplay of interests, but the interplay of meanings. Individuals are not representatives of classes or interest groups; they are channels through which meanings circulate throughout society. Subsequently, these meanings will underpin the identification of relevant issues and the formulation of discourses to address them. Therefore, and this is a purely Habermasian statement, whenever one speaks of communication, one refers to widespread debates, these "'subjectless forms of communication" (Habermas, 1996, p. 135-136) which can always lurk behind the launch of official programs. We are dealing with the everyday political life described by Geertz (1973, p. 316):

> "The political processes of all nations are wider and deeper than the formal institutions designed to regulate them; some of the most critical decisions concerning the direction of public life are not made in parliaments and presidiums; they are made in the unformalized realms of what Durkheim called 'the collective conscience' (or 'consciousness'; the useful ambiguity of *conscience* is unavailable in English)."

Even though the *critical mentality* depends on *personal formulations*, it also has its social and historical sources (as shown in Chapter 6). Thus it is possible to argue that this approach to clinical trials is not destined to fade away. In a sense, it has become as "traditional" as other mentalities. On this point, Arendt's (1963) conclusion, derived from the analysis of the American Revolution, can be instructive: traditions are much harder to be broken than forms of government. Anchored in global processes, the *critical mentality* can now emerge in different cities and countries.

Thus it would be imprecise to consider ethics committees as a sort of global community. Rather, mentalities must be seen as global communicative communities. For example, the holders of the *technical mentality*, whether they review protocols in Porto Alegre, Pretoria, São Paulo or Cape Town, mobilize similar concepts, search for similar issues in research proposals, are informed by similar concerns with scientific standards and expect that a similar scientific progress will eventually derive from global trials. Even though the *background knowledge* plays a minor role for them, background assumptions do not completely disappear here. At the same time, these people also share the contents of a *foreground knowledge* that is decisively shaped by medical, biological and statistical concepts. In this sense, the *technical mentality,* as well as other mentalities, constitutes a global community of meaning.

I am not arguing that committee members debate for society. Even though, from an administrative point of view, they might be seen as representatives of research subjects and researchers, this is not the case in a communicative interpretation. Mentalities are not formed within committees, even though they become stronger and more *real* when adopted by committee members. These members are not speaking for society; rather, they are speaking with claims and concepts formulated through social processes. They are neither inventors nor receptors of claims; they are channels through which claims circulate and resonate. As

Denzin (1997, p. 39) put it, the other to whom I talk and I are engaged in a social context: “Together, we create a historical situation, a social structure, a moment of experience, and enlivened culture.”

In this sense, ethics committees potentially play a crucial institutional role. Being permeated by meanings that cross over society, they guarantee, to at least a small degree, the occurrence of democratic debates. As explained by Habermas, political debates must be solidified through the production of law and institutions in order to obtain legitimacy. “[...] ideas produce effects only throughout the idealizing presuppositions of established or institutionalized practices. Only when the practices have acquired a foothold in legal institutions, for example, must the fictions or presuppositions on which participants operate be taken seriously as facts” (Habermas, 2008, p. 334). In this way, ethics committees can be seen as mediating institutions, for they are midway between everyday, ordinary ideas carried by citizens, and formal, precise policies carried out by government agencies.

In Chapter 4, it was seen that the South African Medicines Control Council (MCC), by implementing the “capacity-building” policy, is trying to reduce the inequalities between research sites, as well as between black and white physician-investigators. This policy can certainly be interpreted as the effect of communitarian concerns that circulate throughout South African society and are reinforced by South African ethics committees. We are dealing with the “communicational flow” pointed out by Habermas (1996): concerns crossing over society have reached the core of the political system and led to official policies. In the South African case, the MCC’s measure has already provoked the first changes in the country’s clinical research system (like the inclusion of some new settings and researchers into international studies), representing a certain success for holders of the *communitarian mentality.*

These considerations can have important consequences for sociological (and communicative) explanation. Over the last years, the “sociological imagination” (Mills, 1959/1970) has been sometimes threatened by the use of concepts that are not in tune with society’s contemporary configuration. For instance, sociologists tend to disregard the crucial lesson of Arendt (1958/1998), according to which the old division between private and public is no longer meaningful and explicative for sociology. Habermas (1996) himself kept speaking, for many years, of a “public sphere,” thus making his communicative theory less communicative. The concept of mentalities

seems to capture the nature of current social debates, in which public and private aspects are forever intermeshed. Indeed, mentalities cannot be "public" (becoming socially available and meaningful) without being, at the same time, "private" (being nested in the individuals' internal axiological universe).

These are the basic clues for a communicative explanation of clinical research and ethics committees, as explained in the following section.

7.4 A COMMUNICATIVE APPROACH TO ETHICS COMMITTEES

Due to the goals of my study, this thesis had to be, for its most part, composed by sociological, philosophical and historical descriptions. Little space remained for the advancement of an original explanation, whose development would require many more chapters. However, it seems to me that my descriptions indirectly provided some clues for what would constitute a communicative approach to ethics committees. This approach would be characterized by two main traits.

Firstly, a communicative explanation would emphasize the symbolic dimension of ethics committees. As explained in the previous section, the ethical review system has acquired formal structures with which one can signal concerns with scientific seriousness and legal responsibility. This aspect, which constitutes an ancillary aspect in other sorts of explanation, would be at the core of a communicative explanation. Even though committees may fail to fully accomplish their scientific and ethical tasks, they serve as a cultural (or ideological) indicator of the accuracy of trials. The globalization of the ethics committee model reveals that even at the international scale, clinical research must be socially justified by means of formal structures capable of conveying the fairness and precision of studies.

Secondly, a communicative explanation would necessarily incorporate the dissensions focused on by Habermas' theory of communicative action. Therefore, the interpretation of ethics committees cannot be carried out without considering that they serve, at the same time, *instrumental* and *communicative* purposes. In other words, they help resonate not only (instrumental) concerns with principles, progress and cure but also (communicational) concerns with individualities, social responsibility

and political changes. Thus, one should consider the interplay between all the mentalities described in this thesis.

This perspective can be considered as an innovative aspect of my study. So far ethics committees have been framed through one-dimensional approaches. Some analyses emphasized institutional commitments and the *pragmatic* dimension of committees (Rothman, 1991, Bosk and Frader, 1998, Bosk, 1999/2008, Dixon-Woods et al., 2007, O'Reilly et al., 2009, Kohlen, 2009); some pointed out the social situatedness and the *communitarian* dimension of committees (Eckenwiler, 2001); some stressed procedural and moral difficulties, highlighting *bioethical* tasks (Nyika et al., 2009); some suggested a moral assessment of trials that would be inspired by the ideas of progress and societal advantage, thus foregrounding *technical* aspects (Jonas, 1969).

The theory of communicative action is the only explicative framework that allows us to work on a multi-dimensional basis. In other words, it enables us to recognize that committees, rather than being informed by one single rationale, are actually permeated by different rationales, which may reinforce or weaken each other. Even though some *rationalities* come to be ideologically hegemonic, a diversity of approaches never cease to exist within committees. From a communicative standpoint, an accurate explanation of committees has to point to aspects such as diversity, interpretations, negotiations and dialogues.

In this way, it is possible to see that communicative processes can never be dissociated from political and economic processes. Globalization has been framed as a mighty process that would eventually submerge biological life in its sea of manifold risks (Beck, 1986/2005, Nowotny et al., 2001/2007). Nevertheless, one should not forget that globalization implies not only political and economic changes, but cultural ones as well. However severe the threats to biological life might be, global research and development seem to carry, nowadays, a much more concrete danger: the annihilation of alternative ways of living and thinking, through the diffusion of the *instrumental rationality*. The main challenge of sociological explanation is not the provision of the ultimate definition of ethics committees, but the formulation of descriptions that help grasp the coexistence of different definitions within committees.

The fact that committees are composed by diverse people with diverse backgrounds and life stories is not a minor feature of a collective body from which

unified actions and visions might somehow be expected. This personal diversity is, indeed, the source of an ideological plurality that guarantees a certain degree of vitality in committees. In a world threatened by ideological homogeneity, explanations that unravel heterogeneous aspects can only be disciplinarily and politically beneficial. With the right view and effort, it is possible to stress differences between standpoints and construct (institutional, legal, cultural, artistic) mediations among them, allowing for fruitful dialogues.

In this sense, the methodology chosen in this study proved useful. The conduct of individual interviews allowed committee members to give utterance to claims full of cultural and political meaning. At the same time, the comparison between committees located in different cities and countries made it possible to capture aspects of discourses that go beyond local and national frontiers. Nevertheless, this methodology could not avoid having its limitations. The practicalities of the fieldwork led to the formation of a group of interviewees in which physicians were somewhat under-represented. Even though physicians constituted the largest group of interviewees, when we look at each committee individually, the proportion of physicians intrerviewd remained below the proportion of physicians in the whole committee. In addition, the study of a traditional location of global trials (the United States or a Western European country) could have enriched the analyses presented previously. In spite of these main limitations, it was possible to detect and scrutinize some important ideological trends in the universe of global trials.

7.5 GLOBALIZED IDEOLOGIES

The *instrumental* and *communicational rationalities* inform not only practical actions but also discourses and mental life. However, from the viewpoint of individuals, they are too broad to be assimilated. To be sure, whenever one voices a technical discourse, for instance, we could say that the *instrumental rationality* is expressed. However, this description would be as precise as saying that when one person breathes, he or she is aspirating the earthly atmosphere. Even though the atmosphere forms one single element, it is known that depending on the place, there are many differences in terms of air pollution, air quality, humidity, and so on. Equally,

rationalities are not a continuous phenomenon, but have "discrete levels" (as physicists would put it), sorts of *quanta,* which I am calling *mentalities.*

The concept of mentalities is endowed with a considerable analytic import. Especially, it constitutes a theoretical mediation, allowing the conduct of empirical analysis moving smoothly from broad theoretical concepts to specific empirical situations. In this way, it is no longer necessary to force abrupt interpretive passages, suggesting, for instance, that a particular discourse or action is the manifestation of instrumental rationality. For rationalities cannot be realized without mediating steps through which mentalities are constructed and through which local processes are connected with global processes.

Conversations between *rationalities* and *mentalities* are frequently dependent on national processes. Since its beginning, the globalization of trials has happened as the diffusion of tendencies, guidelines and procedures from country to country. In addition, regulatory frameworks, and the ethics review system itself, have always been organized nationally. Therefore, the country and the national state can only be decisive references for social actors who build up discourses about clinical trials. In the previous chapters, I quoted some examples in which committee members spontaneously advanced claims such as "Here in South Africa" or "In the case of Brazil."

Thus, in a communicative explanation, the state is another element, and a decisive one, of mental life. Indeed, as Anderson (2006) teaches us, states hold communities that are not natural, being instead "imagined." Without renouncing a political approach, we do not need to mobilize concepts such as civil society, classes or public spheres. The notion of meanings circulating throughout society can be compared to Sartre's (1960) idea of "projects": they are, at the same time, cognitive structures and supports for concrete actions. Once again, we can compare the concept of mentalities to "styles of reasoning," as proposed by Hacking (1990, p. 6): "[…] the growth of a style of reasoning is a matter not only of thought but of action."

As claimed in Chapter 5, holders of the *technical mentality*, on the one hand, and holders of the *analytical mentality,* on the other, are sociologically relevant not only because they reinforce two different ideological structures but, mainly, because their discourses frame the management of global trials in ways that, in many aspects, contradict each other. In Brazil, as seen Chapter 5, the current reformulation of the

ethics review system has opened up some leeway for analytical/critical views to emerge and try to reshape the Brazilian system, which has been marked by bioethical concerns.

Nevertheless, the communitarian, analytical and critical approaches have been decisively weakened by their little ability to permeate collective actions, as well as their weak representativeness in consolidated institutions. In contrast, the bioethical and technical approaches have been adopted by different institutions (such as medical associations and bioethical societies), while the healing approach has received nothing less than the trials industry's sanction. Consequently, from a political point of view, imbalances emerge between mentalities, because:

> "Ideas [...] must, as Max Weber, among others, never tired of insisting, be carried by powerful social groups to have powerful social effects; someone must revere them, celebrate them, defend them, impose them. They have to be institutionalized in order to find not just an intellectual existence in society, but, so to speak, a material one as well" (Geertz, 1973, p. 314).

Thanks to the hectic, and sometimes chaotic, ways in which global trials have been brought to countries like South Africa and Brazil, it is impossible for individuals to formulate discourses that do not express, at the same time, different approaches to clinical research. Thus a clear-cut classification of individuals, based on ideal types, would lack precision. This finding is similar to the one obtained by Felt and Focher in their study on the views held by people about scientific governance. Two main ideological models were identified, but research participants did not remain exclusively attached to one particular model. "Participants thus switched, deconstructed, reassembled and hybridised elements of models" (Felt et al., 2008, p. 320). The mentalities described in my thesis also allow for these examples of ideological flexibility.

However, two aspects must be taken into account. Firstly, for each individual one type of approach is stronger than others. Secondly, yes, it is difficult to capture the political side of global trials and discourses by focusing, exclusively, on individual interpretations; it is rather necessary to pay attention to geographical scales. The *communicational rationality* is stronger at the local scale whereas the global scale is

the *instrumental rationality*'s realm. In other words, communicational meanings will be stronger whenever individuals are decisively engaged in, and concerned with, contextual matters (epidemics, transport, hospitals' research structures, exchange rates, among others), whereas instrumental meanings are stronger for those who foreground global matters (scientific standards, statistical aspects of trials, universal principles, among others). That is also why physician-investigators, who are often interested in issues such as knowledge of diseases and scientific advancement, tend to hold technical views.

In this way, globalization becomes a central characteristic of mental life. Even though mentalities can assume different contents depending on the place, they tend to be globalized, playing their typical roles in different contexts. Arguably, the occurrence of mentalities transcends the field of clinical trials. Indeed, interesting sociological studies could derive from the analysis of the (pragmatic) discontentment against global finance; the (bioethical) discussions about the globalization of research on stem cells; the (technical) discourses pointing out the progressive role played by financial institutions; the (healing) initiatives to protect the endangered natural environment; the (communitarian) initiatives aimed to soften the hardships of poor people; the (analytical) efforts to unravel dietary malpractices incited by the globalized fast food industry; or the (critical) views that campaign for drastic reformulations in the network of supra-national institutions. Thus individuals never cease to be confronted by debates that have something to do with global processes. More than ever before, the phenomenon identified by Simmel (1903/1950) takes place: urban life amounts to a huge ideological stimulation.

It is indeed important to note that urban life has become an appropriate scenario for mentalities to be formulated and dispersed. As I claimed elsewhere (Bicudo, 2011), the big city provides the trials industry and researchers with the needed research infrastructure. It is also in the big city that we find manifold relations, enterprises and means of communication, forming the "communicational densities" pointed out by Santos (2000). This favours the circulation of ideas and expectations, reinforcing mentalities. As Geertz (1983) explains, everyday knowledge is generally equal to knowledge of the lived space, constituting a "local knowledge." At the same time, as noted by Santos (2000), the local scale and its contents (which includes

ideological products) are more and more dependent on processes happening at the global scale.

The final outcomes of the relationship between *rationalities* and *mentalities* are not to be seen within individuals but within territories and states. Individuals participate in the globalized process in a discursive, ideological manner. As for their concrete lives, they continue to be decisively attached to concrete places. Thus they are not "world citizens," but people engaging in local contexts and receiving some specks of globalization in the form of discourses, promises, claims and ideologies. Multinational companies and CROs, in their turn, operate at the global scale, making choices and taking relevant decisions that affect the destiny of many countries. Moreover, and in spite of persistent discordant views, they have been quite successful at promoting an ideological domestication that threatens the autonomy of ethics committees. Critiques and analyses continue to smoulder, but nowadays, they have to hold out under the sway of increasingly powerful waves of standardization.

Appendix 1:
Structure of the interview

The topics underlined were addressed in all the interviews.

1. Interviewee

Name

Professional background

Professional activity

Years in the committee/Previous experience in ethics committees

2. Joining the committee

How the interviewee joined the committee

Invitation? From whom?

Why accepted the invitation?

The reasons why the person was invited

Knowledge of the committee at the time of joining it

3. Social relations

Do your colleagues know you are a committee member?

Do you introduce yourself as a committee member?

Do you have friends in the committee? Is that somehow good or bad?

4. Ethical review

Do you review protocols?

Of which type (qualitative studies, drug trials)?

How many per month?

When do you review?

5. Views about the review

Is it necessary to have a medical background?

When reviewing, what is your main concern?

When reviewing, do you think of the research subjects?

Is the review a subjective activity?

Is there any part of the protocol that is more important?

Is there any type of protocol which deserves more attention?

Would it be good to observe the actual research procedures?

6. Meetings

How is the atmosphere?

Do you always attend?

Do you remember a big disagreement in a meeting?

Are you always at ease to speak?

Is the meeting the most important thing?

7. Payment

Should committee members receive payments?

Do you consider your activity as work?

8. Clinical research

What is the main goal of clinical research?

Is the expansion of clinical research a good thing?

Is there a difference between academic and industrial research?

9. Committees

What is the role of ethics committees?

Are they equipped to play this role?

10. Final questions

Has your view about drugs and medicines changed as a result of your activity in the committee?

Today, what is your motivation to be in the committee?

What is the advice you would give me for me to be a good committee member?

Appendix 2:
List of claims and mentalities

I am listing all the claims identified in my study. I present the groups of claims (which appear on my *discourse graphics*), as well as each particular claim.

PRAGMATIC MENTALITY

PRAG1

Institutional interests: physician-investigators are motivated by institutional and economic interests

PRAG2

Committees and interests: Institutional and economic interests affect the ethical review done by ethics committees

Hierarchies and committees: power relations and hierarchies affect the operations of ethics committees

PRAG3

Financial interests: the trials industry is motivated by financial interests

Access to medicines: Due to high prices, products deriving from clinical trials cannot be accessed by most people

BIOETHICAL MENTALITY

BIO3.5

Scandals in trials: stories of past abuses in clinical trials

Cheap countries: it is cheaper to run clinical trials in countries like South Africa and Brazil

BIO4

Risks and benefits: in every clinical trial there is a risk-benefit ratio

BIO5

Bioethical protection: vulnerable people must be protected by ethics committees

BIO6

Bioethical guidelines: national and international guidelines enhance the ethical review

BIO7

Bioethical committees: committees must put bioethical principles into practice

Committees and expertise: committees benefit from the presence of different professionals with different expertises

Bio-pedagogic committees: in committees, people learn reviewing techniques and bioethical principles

Bio-pedagogic meetings: in committee meetings, people learn reviewing techniques and bioethical principles

BIO8

Full information: committees must make sure that research subjects are provided with full information about participation

Free choice: people must join clinical trials by taking free decisions

BIO9

Reviewing techniques: reviewing research proposals depends on techniques that can be transmitted and assimilated

Ethical training: examples of interviewees that did courses on bioethics

BIO10

Principlism: references to bioethical principles that inform the work of my interviewees

Perennial ethics: bioethics is a field that is always developing

TECHNICAL MENTALITY

TECH10.5

Universal science: there is no fundamental difference between different types of research

Universal ethics: the ethical reasoning can be used to assess any kind of research

TECH11

Enhancing knowledge: in clinical trials, one gathers scientific knowledge of bodies, diseases and drugs

Borderless science: scientific knowledge goes beyond national frontiers

Technical guidelines: regulations belong to broad scientific structures that make it possible to gather scientific knowledge

Research and progress: progress can be realized only through research

Moral science: the doing of good science is a moral duty

Scientific standards: in order to do good science, scientists must comply with objective scientific standards

TECH12

Technical methods: the methodology of research proposals is a pivotal aspect to be looked at in any ethical review

TECH13

Technical committees: committees help researchers improve and develop their studies

Competent review: the ethical review is better when it is done by reviewers with scientific expertise

Technical hierarchy: the scientific assessment of proposals is more difficult than their ethical review

Techno-pedagogic committees: in committees, people learn the scientific design of proposals

Recognizing expertise: committee members stating that they not feel confident to review drug trials because they lack scientific expertise

TECH14

Accurate trials: pharma companies have money and expertise to design excellent clinical trials

Scientific hierarchy: industrial studies are more properly conducted than academic ones

HEALING MENTALITY

HEAL15.5

Healing research: taking part in research is therapeutically beneficial for subjects

Blocking standards: too stringent regulations are making the conduct of research become too difficult

HEAL16

Healing trials: clinical trials aim to generate medicines and therapies

Beneficial trials: clinical trials aim to improve the people's quality of life

HEAL17

Healing committees: committees help develop medicines and therapies

Healing-pedagogic committees: in committees, people become aware of new medicines and therapies

HEAL18

Humanitarian research: research is done for the sake of humankind

Perennial research: there are always things to discover and improvements to be done

COMMUNITARIAN MENTALITY

COMM3.5

Cheap countries: it is cheaper to run clinical trials in countries like South Africa and Brazil

Global shopping: it is easier to meet regulatory requirements in countries like South and Brazil

COMM4

Global inequalities: in clinical trials, inequalities between countries are manifested

Distorted research: trials designed in developed countries do not fit the context of other countries

COMM5

Communitarian protection: vulnerable people must be protected by ethics committees

COMM6

Uncertain research: clinical trials bring about insurmountable uncertainties

Hazardous shift: the passage from health care to clinical research involves uncertainties

COMM7

Communitarian committees: committees defend the community's integrity, looking at research proposals from the viewpoint of research subjects

Committees' funding: concerns with shortages of resources in committees

Concrete ethics: ethics is learnt not only by studying reviewing techniques but also by experiencing the everyday life of committees

Communo-pedagogic committees: in committees, people learnt several aspects of trials' practicalities

Altruistic members: committee members do a service for the community

Review time: committee members need to give some of their time to the committee

COMM8

Protecting bodies: studies with invasive procedures deserve more attention from committee members

Protecting samples: concerns with biological samples being taken, stored and exported

COMM9

Concrete studies: concerns with particular procedures and costs of trials

COMM10

Poor subjects: concerns with poor people taking part in clinical trials

Age and trials: concerns with research on children or elderly people

Illiteracy and trials: concerns with poorly educated people taking part in clinical trials

ANALYTICAL MENTALITY

ANALYT10.5

Social trials: trials affect not only personal relations but also the organization of society

Underserved subjects: concerns with people who take part in trials because they do not have access to health services

Sick subjects: concerns with severely sick patients who frame clinical trials as a therapeutic scapegoat

Communitarian work: examples of committee members who work for national or international communitarian programmes

ANALYT11

Flexible standards: scientific standards allow for different arrangements, according to one's interests

ANALYT12

Analytical methods: the methodology of research proposals is a pivotal aspect to be looked at in any ethical review

ANALYT13

Analytical committees: committees have to avoid the conduct of trials of no social worth

Analytical-pedagogic committees: in committees, people learn the methodological tricks used in clinical trials

Overlooking hierarchies: those who lack a medical background are also able to assess drug trials

ANALYT14

Analytical guidelines: based on current guidelines, members can detect flaws and inaccuracies in research proposals

ANALYT15

Giving examples: committee members citing particular trials and methodologies used in past studies, excluding studies reviewed by themselves

Quoting texts: examples of committee members citing ideas or data they found in texts

Comparative view: examples of committee members comparing clinical trials with other types of research, or comparing national situations

Analytical training: examples of committee members who did courses on scientific or statistical aspects of trials

CRITICAL MENTALITY

CRIT15.5

Over-consumption: trials are used as strategies to promote medicines that are not really necessary

Analyzing guidelines: examples of committee members scrutinizing guidelines on clinical trials

CRIT16

Criticizing committees: examples of committee members pointing to flaws in the ethics committee model

Criticizing bureaucracy: committee members criticizing the heavy bureaucracy of the ethics review system

Criticizing guidelines: committee members criticizing national or international guidelines on clinical research or ethics committees

CRIT17

Inaccurate trials: trials conducted by the industry tend to contain methodological flaws

CRIT18

Defying hierarchies: renowned researchers and powerful companies can also design flawed research proposals

Appendix: 3:
Full transcript of one interview

Committee: 7

City: Cape Town

Date: 05 July 2011

Duration of the recording: 55min36s

Professional background: social scientist

Years in the committee: 4

Gender: female

Code used in the thesis: Cape Town/C7Social scientist/07-11

The interview is presented in a table. The first column displays the full transcript. The second column contains the quantitative analysis, showing the claims advanced (see Appendix 1) and the scores attributed according to the type of claim (see Table 2.5 on page 55).

As for the type of claims, the following acronyms were used: Central claim=CT; Ancillary=AC; Confirmatory=CF; Indirect=ID; Repetitive=RP.

BEGINNING OF RECORDING *So today is the 5th July (already!), this is the committee seven, the interview with [interviewee's name]. Okay... So you're a social scientist. Okay. And you studied here in Cape Town.* Yes. [Confidential information.] *And how long have you been in the ethics committee?* Since 2007. *Ah okay, four years. Okay. And is it your first experience in a committee?* Yes. *Hm. Okay. Did you do any course on bioethics?* No. I've always felt bad that I don't really have a formal ethics training. I don't have a recognized ethics certificate of any sort. That sometimes has concerned me. How much training should you have to go onto... You know, you often get fixed questions. Would more training help? That kind of thing. So I have no real formal training. *But do you think it would be good to have formal training?* I think so sometimes. I'm not sure. I don't... I don't know if it always addresses the questions that you encounter in the meeting. Would a formal training help that?	
But are you in the meeting as a... How can say... a layperson, a non-specialist. Are you considered as a lay member in the committee?	

We do have two people from what they call the community. So we are more... I wouldn't say I am... What is good about the committee is that it does include people from other disciplines. So our, sort of, role, I think, are the issues around vulnerability and also issues around the definitions of populations. Are they varied? It is fluid. It could vary from, you know, contexts. And the local and global thing. You know, sometimes what is perceived as a definition of population in America might not be the same sort of thing that we would do here 'cause of these social constructs and these kinds of things. And even in Brazil it could be another different, sort of situation. So I think it is those kind of issues, the context, that kind of thing, that we look for. *Why do you think they invited you to join the committee and not other social scientist?* [Confidential information.] It might have been because of my boss. [Confidential information.] He's had a long association with the ethics committee. Maybe it was on the basis of his suggestion, I don't know. But... I must say, it's been an extraordinary and enriching, in many ways... I've learnt an awful a lot, to be in a multidisciplinary, sort of, situation, grappling with issues. And, you know, you not always have the answers. *But when you were invited to join the committee, did you know the role of the committee?* From being on the other side, from being a researcher we know the committee. Not from inside. And this sort of formality, I think, in terms of ethics committee and the way that it is changing, also in social sciences and humanities, it is not as... This committee works very hard, you know, and it is very well organized administratively, but I think it is because of the amount of research that comes through, funded research in health sciences. So you know that the sort of workings of the ethics committee will vary. You know, they vary in the social sciences. So I had an idea of it, but I wasn't sure of exactly how it would work.	Communitarian committees (CT)-3
Somebody told me (I don't remember who told me that) that is good to belong to the committee because it is good for the CV. Do you think so? I'm not sure [laughter]. I think, you know, any committees that you belong to would be good on the CV. It tells, I would imagine... I don't really do a good CV, so [laughter]... But I think it says that I do things for the university that are not only research and teaching, I'm engaged in, you know, some other work that isn't... I'm giving up myself to the university. So I think on that point it is saying something. People say it is good on your CV. It could be [laughter].	Communitarian committees (CT)-3
Your colleagues know that you're on the committee. Not all of them. It is not... I don't... It is not something that comes up in conversations, often. And I'm not terribly sure if I want them all to know [laughter], then in case issues come up and they come to you and they say: 'Why is this happening?' [laughter] But it is not something that comes up in conversations. But I think the association... Few people do know that... And it worked for me in many ways. It is having... I've learnt a lot and [name of the committee's deputy chair] is extraordinarily good in the sort of academics of an ethics committee as well. She always has the right answers if you have a query, and she always comes out with this... You know, she is always available to discuss issues. If you have a review and you've got questions and so forth. Always available. Very, very supportive and committed. So those kinds of things I find... That where the benefit to me is. It's opened up sort of areas.	Committees and interests (AC)-2 Concrete ethics (ID)-1
Is there any situation in which you introduce yourself as a committee member? I don't think I know... In some... I think... In a... It's been, I suppose, seminars. But they've been, largely, people from different kinds of ethics committees. The last time I raised this it was a cross-disciplinary ethics	

committee meeting. *In Cape Town.* Yes. And they came from, you know, computer sciences, social sciences, business school and all of that. And that is when I introduced myself as a member of the committee. But otherwise I can't remember. *Okay. So you're a reviewer.* We do review, yes.	
Okay. And do you reserve some part of the week or the day to review protocols? I usually do it in the weekend. I find they take quite a bit of time. And you need some sort of dedicated time to it. So you know, it is... It is reading through first and then... You have to read through a few times, I would say. I find that clinical trials are hard because sort of I don't know all the ins and outs of clinical trials so well. But there are, certainly, some people on the committee who are able to do that and there also other people in the university. It is not only members of the committee that review. It also goes out to the university. So...	Review time (AC)-2 Competent review (AC)-2
But do you review any particular kind of protocol? Usually, the ones that come to me are sort of social sciences things. You know... HIV raises lots of social questions, those issues around... you know... So those kinds of things would come. Research with disabled people, research with children, those kinds of issues. There is more and more research with children. So it is those kinds of issues. And those are the sort of areas where things change, you know, national institutions are changing rules on, you know, children and dissent and consent and things like that and the change in which... So those kinds of things are where [the committee chair and the deputy chair] are very up-to-date in everything that is happening. I feel very comfortable with this committee. They're nice people, you know, they're very... It is a good crowd of people. [Confidential information.] Sometimes, days after the meeting, the whole questions that came up... Sometimes they don't leave you because you don't always resolve them ethically. There is a resolution but it is never... It could have gone on and on the debate, do you know what I mean? So sometimes it... But reviews do take time.	Review time (AC)-2
Are there people in the committee that you consider as friends? Hm. I would say... And sometimes I think to myself that I don't know how they would feel. But I think I feel comfortable... I have a colleague, [name of one committee member], whom I think I could ask... Because I suppose it should be someone you could make a full of yourself. So there are, I would say, I could ask [the committee's deputy chair] any questions that might make me look silly but she would understand. And I think I could do that with [the aforementioned committee member]. So there are people who... with whom I share sort of philosophy, I think, about things. I would certainly have... [The deputy chair] I can ask... She's recently done me a huge favour. [Confidential information]. So [in research] there are all sorts of issues of *trust* along the way. So ethics is a big thing but... You know, it is not an easy thing to teach people because of all the concepts and things. So she and [a third committee member] gave me a lot of time recently to explain... So in things like that she would be very supportive as well. You know, watch me, I can go to all sorts of themes, so keep me focused on your interview [laughter].	Concrete ethics (ID)-1
No [laughter]. Is there any average of protocols that you review per meeting, per month? I suppose, not more than one. They're very. They spread them. They don't ask for more than that. *And that is good because you have time to read carefully...* Yes, exactly. They don't overload.	
Okay. And do you think a member who doesn't have a medical background	

could have some difficulties at reviewing a protocol? I think, again, it is... We have people who don't... I think so, there are certain protocols that I would not be able to review... *For instance.* Clinical trials, [pause] vaccines, you know, this sort of more medical issues around those kinds of things. But in a sense, I suppose, that depends on the sort of distribution of the people and the availability of others they can draw on. They do get... And sometimes two people will review a single protocol. And they... Do you know how it works? There is... We all get the summary and... So if you review, you can review the whole protocol but then a time before the meeting, you get all the summaries plus the research instruments and the consent forms. So those are... I'm sure it is the same in many places. So those things take time to... Because some of the consents [consent forms] are very big. *And when you're reviewing a protocol, what is your main concern?* Hm... It is... I suppose, in a sense, it is that the people will know... First of all, it is there is a sense of... that people will be informed about what is going on. So it is to know, myself, what they're doing, what the researcher wants to do, and to make sure that all that information will be available at a level of language that they [the subjects] understand. Often, protocols or consents tend to take quite a stiff language instead of... There is not enough explanation, you know, they talk about the [Declaration of] Helsinki... People don't know what all those things are about. And I also like... We've got a... It is the good... Hm... What is ...? Standard operation procedures. I never remember that. *S.O.Ps. [laughter].* Yes, that is right [laughter]. And there is a suggestion number one to use a number of questions to reflect back with the person who is being interviewed, just to check whether what you're saying people understand. 'Cause in my [research] experience, it doesn't always happen that people understand straightaway. Even people that I work with in my own research don't even know what research is. You can't just do something, you have to test it first. So there is a whole kind of consent and things to get through and how do you do that in a language that people understand in enough space that you don't lose them.	Recognizing expertise (CT)-3 Review time (AC)-2 Full information (CT)-3
Do you think that reviewing a protocol involves a subjective aspect? Yes. I think that all things always involve a subjective aspect. It is both. But it is always something that...if it [the protocol] is well written, if it is attractive, if it is not well written... You know, these things that you start to make decisions about before you've even worked with it. If they leave track changes and, you know, if the references aren't done properly. In some ways, it is like marking, although... Because you're practising marking, you can't help raising issues like that. I don't like to... One of the hard things to me is reviewing a protocol from another discipline, even if it is another humanities or social sciences, because you're not sure... Different disciplines would emphasize different things. So I think you need to say things carefully. And I think it is useful... I always find it helpful if a reviewer has made suggestions that would improve my protocol. So I do it... I try to do it in that kind of spirit. But I think there is a subjective aspect to everything I do. You know, the choices you make as a researcher, the things you chose to research, where you want to work. You know, I could have said no to going to the ethics committee. So all of those things... I don't know where subjective begins and objective ends [laughter].	Concrete ethics (CT)-3
Yeah. And do you think there is any part of the protocol which is more important from your point of view? Hm [pause]. I'm not sure. I think there is... Hm. I think, sometimes, as a social scientist, an informed consent is a kind of a ritual, in the sense that... But I think it is very important, even though there are questions in social	

sciences as whether you should have signed consents, 'cause some people don't sign... 'Is it embarrassing?' You know. 'Is it always appropriate?' If you're participating and observing, you can't sort of ask the whole of the clinic to sign a consent. So... But I still think that that forces... The fact that you do have a consent [form] to read out or discuss forces us to stop and inform. I think research can be very intrusive. I think we have to put some limits on researchers sometimes, especially amongst poor people, because we assume sometimes that poor people will have time for us, and what we sometimes ask poor people we will never ask a lawyer or a doctor. We wouldn't ask them for two hours of their time. We would have to pay a lot. So it is those kinds of issues, I think. *So, really, poor people would be more vulnerable.* I think so. It is... On the other hand, you can't say that they won't be able to make decisions on their own, hm! I think it is about making sure that they are well-informed to make a proper decision. *And do you think it is easier to inform someone who has a higher educational...* No, I don't always think so. I find it hard to understand some of the consent forms and protocols. If I was in a clinical trial... You know, if someone asked me to come on to do some medical... to test some drug, I would find it difficult to know all the ups and downs that might be involved. So I don't think it is... I think everybody needs to be informed.	Communitarian protection (CT)-3 Bioethical protection (CT)-3 Poor subjects (CT)-3 Discursive protection (CT)-3 Free choice (ID)-1 Communitarian committees (ID)-1
Okay. And do you think there is any type of protocol that deserves more attention from an ethics committee? I think the ones with vulnerable groups. But what is a vulnerable is also a thing to question. But... I wouldn't know that. I think they [protocols] all need... Some can be expedited. They are likely to this. For instance, it might just be... they don't involve intrusive things. For instance, taking blood from children. 'Is that necessary?' I think those kinds of issues around. But, you know, watching children playing or something would not be an intrusive issue unless it was in a very private space, for instance to hung around and observing someone's home would be an intrusive thing to do. So it is... There are many things but I think things like, you know, how much you're going to... taking blood. I think those issues. I would be concerned about making available... I have concerns about, you know... I know open access is a good thing but making available, you know, all the biological material from South Africa into, you know, the hands of the first world... You know, we just don't have the same access and skills, and they will in the end, you know, get the benefit of having all that kind of information. Do you know what I am saying? Those are the kinds of things that... I am going out of the subject. But there are, I suppose, concerns about vulnerable groups and sort of intrusive activities.	Protecting bodies (AC)-2 Protecting samples (CT)-3 Age and trials (AC)-2 Global inequalities (ID)-1
How would you describe the atmosphere of the meetings? Supportive. I don't think... The point is to facilitate the research, not to be a gatekeeper. It is not to... That is what I appreciate about it. Not all protocols will go through in the first time but they [committee members] are not there, really, to throw them back. It is, if you need what it is necessary to get it through... It is a facilitating process much more than which is often... People outside often assume that it is quite a gatekeeping operation but it isn't. *Do you enjoy the meetings?* Yes, I do. I sometimes become very concerned and... but can you... you know, you wonder if you really are making a contribution. You know, you sort of think, you know: 'Someone else would be doing a better job' [laughter]. There are those days when you think, you know: 'I shouldn't be here.' So I suppose it is those kinds of things. But in terms of collegiality with people, what I've learnt, I have no regrets about it. It is terrible time of the month and the week, but that is...	

In addition to reviewing the protocol, is there any kind of preparation that you do for the meeting? Only reading all the... It is the review that you do. That needs to be handled a week beforehand, and then reading in time for the... That is all the preparation. And reading the summaries. *Do you think the meeting is the most important moment of your participation in the committee?* Hm... Hmm... In some ways, I suppose, it is a sort of outward sign of the commitment, to get to... Sometimes it takes... Sometimes I think: 'Oh, I think I'm not going this time,' but, you know, you go. But I think it is a bit of both [reviews and meetings]. The review takes time... I think it is a bit of both. I think there is a... Say it again. If I think the meeting is the most important... *Yeah. If you think the meeting is the most important moment of your participation in the committee.* I don't think so, I think there is a range of sort of things that make you belonging to the committee. Sometimes I think the meeting could go on happily without me 'cause there are enough people there to make it happen. It is not... It is a big enough committee to...	Review time (AC)-2
You work in the committee is not paid. You don't get paid. No, no. *Do you think the members should get paid for their work?* I'm not sure what the... [pause]. I suppose... You get paid for supervising the thesis. Extra-work. Extra-teaching. I'm not sure about that. I've thought about that sometimes but I'm not sure. You know, it is... Do you think it would still look good on the CV? [laughter] *Not on the CV but maybe on the bank account.* Yes, yes, yes [laughter]. Do other committees get paid? *No, I haven't seen any committee.* Yes, I think it is supposed to be a kind of taking advantage of people's... you know... good will. *But maybe people would feel more committed to work.* This one is committed. I suppose there is a core that is committed. You would have... You could... I don't know, maybe you could pay them for each meeting that they attend. You would probably have competition to attend then [laughter]. *Yes, depending on the salary [laugther]. But do you consider you activity within the committee as work?* Hm [pause]. Yes, I suppose so. It is not fun, you know, it is not... But I don't regret it, I don't... Sometimes I think: 'Oh, my goodness!' You know, you get this big paper pack that comes into your pigeonhole, and sometimes I think: 'Oh, no! There they come.' You know [laughter]. You've got to get ready for those things. But they always ask you if you can review, they don't... They're always... So they ask you if you've got time in the month. So they don't sort of do it without asking but then when you see a new [project] coming, you think: 'Oh, my goodness!' *You review the protocol but you don't have any contact with the actual procedures of the research.* No, we don't have any... We can't... The researcher is responsible for that.	
But do you think it would be good to have contact with the procedures, to see what is going on? Hm [pause]. I'm not sure if... I know this is a sort of... I think of my own research and think to myself: What happens if they come on a bad day when everything is going wrong? Research is like that. You know, you don't arrive and, you know... You like chaotic and looks as if you're not doing anything properly. So sometimes I don't that the policing kind of... I'm not sure if the committee should be a policing issue but I think, sometimes, I know in my own... Sometimes it is tempting to rush a consent [process], because you're in a hurry and you want to get things done. And I'm sure with people like	Full information (CT)-3 Free choice (ID)-1

me, who also... [laughter]. And because I'm on the ethics committee, I sort of feel: 'I can't rush this,' you know. And to train people not to rush, to get people time to think and... even if it is... So I think we should be looking at how people take consents sometimes, who does it, where do they do it, when do they do it. If you can find a private room, should you push it all that you can? Do you snick into a corner somewhere and... I work with people who sign. So you can't actually have a signing consent taken in the middle of a waiting room and no one would know. And sometimes you think: 'Oh, this is just as private...' I often think that he could find a private space, but those are the... But when there is no private space, you think: 'Oh, dear. Do I come tomorrow?' So those are the kinds of... I think consent taking, what is happening at that consent taking... Rushing things. It is tempting to rush things. *In your opinion, what is the main goal of clinical research?* Ideally, it should be better health care, whatever it will make better health care. That is what it should be. Making it possible, you know, without doing any harm. *Ideally.* Ideally. *But in practice... it is not [laughter].* Not always, I think there is... No, I wouldn't say not. I have concerns sometimes. The research that comes through the research ethics committee at the university goes through many, many things. It goes through your carers, then it should go through the department, then the ethics committees, and even the Department of Health. So it goes through many things. But there are... There is research which is carried out that doesn't go through research ethics committees. And that is a sort of thing, you know... I'm sure it goes through *their* committee. How do those committee work? I don't know how they work. There is... Because, you know, there is so much over-research in America, they've moved into Africa and places like that, looking for research populations, and there are those sort of commercial organizations that actually do it for you... *The CROs.* Is that what they're called? *Yeah, CROs.* So that is the kind of thing. What do you... what is going on there? Is it good? I don't know, maybe it is not. They come and they practically got the paper out for you, you know, by the time they finish.	Healing trials (CT)-3 Commercial research (proto-critique) (CT)-3
So over the last years, there has been a big expansion of clinical research in countries like Brazil and South Africa. Do you think that this increasing number of studies is important? I don't know. I sometimes think places like Brazil and South Africa have the infrastructure and the universities and that sort of things to do it, and they don't... The populations in America, in the UK, in Europe no longer are available to do research. They just say no. So they've moved in here to do it. So I think there is a stage where people will start to say no. People will become over-researched. I think there is a point at which too much research... There is a level at which people get over-researched and they know exactly what kinds of questions that people are going to ask. Did I get you question?	Global inequalities (CT)-3
Yeah, yeah. Do you think there is a difference between academic research and the research that is sponsored by the industry? Not always. Sometimes there is and sometimes there isn't. I think that it is one way of departments and researchers getting funds, from the drug companies. But I do feel the drug companies... You know, I would like to, you know, see some of them commit to things a little bit more than they do. They make a lot of money and sometimes they don't always offer... We can't always get the best medicines because of the constraints from the	Concrete protocols (AC)-2

Department of Health. So sometimes, if something works, you may need to sort of see whether those people who were involved in the research, who made it happen, should be looked after for as long as it is necessary. Those kinds of things, I think the drug companies could be more... I think they could pay people more... They don't... 150 Rand, you know... They wouldn't... *150 Rand!? That is the amount?* For... You know, compensating for inconveniences. It is not a lot of money. So if you have to stay in hospital and things like that but I still think, people are concerned, you know, if they're given too much money, they'll only say yes to research. That is the sort of balance. But I don't know. I still think that one should... You can't ask... Rich people would not do it for 150 Rand [pause]. And 150 Rand is not a lot of money any more. *Yeah, I know [laughter].* It is hardly air time for somebody. *But they are not obligatorily paid 150 Rand. They are paid if something goes wrong.* No, no, no, no, no. That is not the insurance thing. *So I didn't understand.* It is for the inconvenience of your transport or your... Those kinds of things. *Ah, okay.* But still, I think you could have more than that. No, the insurances, we do have... There are lawyers on the committee and I think one of them particularly knows those kinds of insurance issues and that sort of thing. But what, you know... Do you have get your insurance? It is really hard to... to prove anything. *And it is 150 Rand per visit. Each time they go to the hospital.* Depending on what... For out-of-pocket for the transport, the... That sort of thing.	Costly medicines (proto-critique) (ID)-1 Poor subjects (AC)-2 Committees and expertise (ID)-1
Okay. And in your opinion, what is the main goal of an ethics committee? The main goal is to prevent harm but also to facilitate research. It is a balance between allowing good research to go on and to protect vulnerable groups and people, to see that there is no harm.	Technical committees (CT)-3 Communitarian committees (CT)-3 Bioethical committees (CT)-3
When you're reviewing a protocol, do you think about the people who are going to participate in the study? Yes. I think that is where I thing the most. *So the participant is not an abstract thing for you.* No. I do... I've been in those situations. You know, I still meet them in my own work. They're not an abstract. *And would it be possible to say that the committee has some duty or responsibility towards the participants?* I think that they do take that... They are aware of that. Yeah. Some more than others. But there certainly is an awareness. Very much so.	
So after four years in the committee, has your view about medicines, medicines and health care changed somehow? Hm [pause]. Not really. I think I started, I suppose, a bit suspicious of drug companies and I probably still am a bit suspicious of drug companies [laughter]. *Oh, yeah? More suspicious now.* No, not really more [laughter]. But, say... I read 'The constant...' What was the name? Before I came... You know the book called 'The constant gardener'? [laughter] *Oh, yeah, yeah. There is a film too.* Yes. *Have you read this book?* Yes, I have [laughter]. I think this was sort of, in a sense... And of course,	Scandals in trials (CT)-3

social scientists are sort of... We're interested in local issues in terms of this sort of political and power of this inter-relationship between the global and that sort of the local. So I think my concerns have always been the relative power of the drug companies as opposed to, you know, the contexts. So those kinds of things are always in my... [laughter] *But don't you think that the power of big companies can be balanced by the power of doctors?* Yes, I do! There is a balance. But you have to... I don't think they're going without being balanced, and I think that is partly what the ethics committee is doing. It is knowing those things. And I think they [committees] do it. *Do you think that your colleagues in the committee are as concerned as you about the power of companies...* I'm sure some of them would say that I was far too worried a bit [laughter]. But that is fun, because that is what the committee is supposed to be. It is supposed to be a range of opinions that sort of balance things up.	Communitarian committees (ID)-1
And do you think that committees, nowadays, are well-equipped to prevent harm in clinical research, in the way they are organized today? I think they do their best but... And I think that... I certainly think they do their best. And whatever they've jurisdiction over, I think they... There is not as much harm or potential for harm... I think there is very... A lot of that, I think is just thoughtlessness, it is not deliberate, that leads to harm. And that is just, sometimes, things you haven't thought about, but something might need more of attention or new ideas that... So I think they do their best. Some harm is bound to happen. You know, it is not bound, but harm does happen. You know, in the sort of... 'Cause research... A lot of research that is not in a laboratory and it is with people often leads to messy things. It is not... You know, it is not neat. It is ups and downs. I think some of the hard job is in that front line, people at the front line who are doing the actual fieldwork. Those are the hard jobs. And whether we give enough attention to that level of researcher... They do get trained, but some people do training a lot better than others, I think, with the fieldworkers.	Uncertain research (CT)-3
Okay. I would ask you two final questions. Today, what is your main motivation to continue to work in the committee? Hm [pause]. My main motivation to work in the committee. I think it is to keep, to know what is going on. I think in many ways, it's been an eye-opener for me in terms of the range of the research and things that are happening, and to see my own role relative to what other people do. And it is very humbling! You know. So in a sense, I think it is the learning side of it [pause]. I don't think as one person, you make a major difference It is, you know, the group as a whole.	Techno-pedagogic committees (ID)-1 Communitarian committees (CT)-3
Let's imagine that I'm going to start working as a committee member. What is the advice you would give me so that I can be a good committee member? I suppose I would say it might be a good idea to talk to the deputy or the chair. Ask them what is expected of you. And then I would... The first review, I would ask someone to have a look at it. And then, after that, I would, I suppose, participate and observe for a while and then I would engage more, in the sense that I see how the debates go and where you think you can make a contribution. I think that happens quite soon, as soon as... It is, I felt, a little intimidating in the beginning, I would say. You feel, you know... In any new situation, I think it is finding what it is going on and finding... You can't explain always. So take a bit of time to find your way and then, you know... and then it gets easier and you feel more comfortable contributing, 'cause sometimes you think, you know, you sort of get the feeling of... of... In a seminar, even, you know, you think: 'Do I make a comment now or don't?' You know, those kinds of questions. And sometimes it is an awkward question because it is going to be debating someone else's views, so you just... But you have to do it, you know, it is part of your responsibility. But I would give myself a bit of time to see how things go, and then you keep	Concrete ethics (CT)-3

going.	
Do you think that, if the committee was composed only by social scientists, you would feel intimated at the beginning as well? Yes. *It is because it was a new situation.* Yes. *Not because of the expertise of the other members.* I don't think so 'cause there is a lot of social scientists that are much more expert than I. I think it is partly finding your labels. You know: 'What is here? What are they...' You can read a lot about ethics and you can do a course in ethics, but the actual practice of the committee is a different thing. It is sort of... It is putting meaning in the whole sort of ethics process and that, in a sense, is what you need to find out about. Are you in an ethics committee at all? *No. No. I've never been in an ethics committee.*	Concrete ethics (CT)-3
[Laughter]. May I ask you something now? *Yeah.* What brought you to this thesis? *It is a long process. Because in my Master's Degree, I studied the pharmaceutical industry. And so I discovered this universe of clinical research. And I wanted to understand this relation between global companies and local contexts. And so I thought: 'Oh, maybe ethics committees are a mediating institution, between the local level and the global level.* It is hard, I think, to be places like South Africa and Brazil, because of that actual job. Because there is people who want to put funding in there and it is tempting for the researchers to get the funds, but, you know, you have to control those ones at the top [laughter]. *Yeah. And that is hard to do.* You have to put limits on them, yeah. Because they've got all the power [laughter]. *Because they are strong [laughter].* Yes. They're second only to the armaments industry. Hm, it is big money! *Yeah.* And they play with poverty. Sickening! [laughter] And how did you. Did you do any participating observation in the pharmaceutical industry?	Commercial research (CT)-3 Poor subjects (ID)-1
No, but I've been talking to people who work in CROs. Okay. *Yeah.* And how do they... END OF RECORDING	

SUMMARY OF QUANTITATIVE ANALYSIS

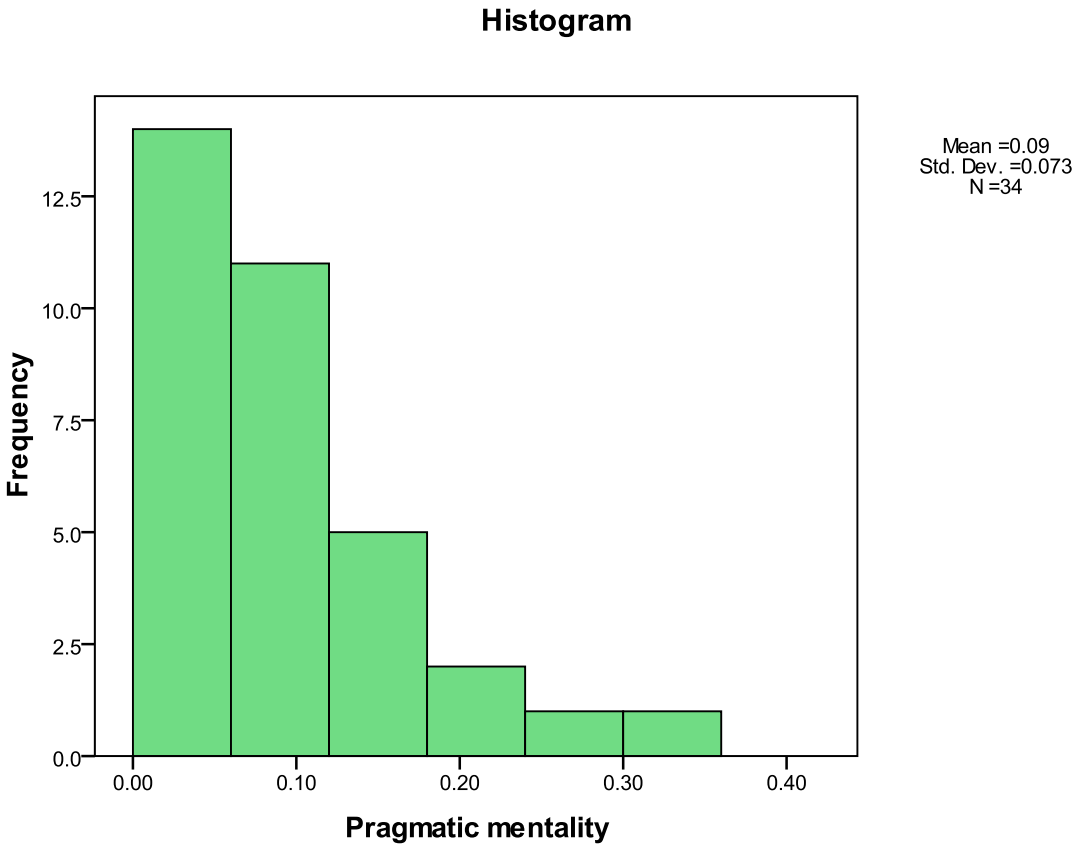
GROUP OF CLAIMS	SCORE	PERCENTAGE	MENTALITY
commercial research-instr. (3)	3	4.6	Pragmatic
commercial research-comm. (3)	7	10.8	pragmatic
interested research (1)	3	4.6	pragmatic
bioethical committees (7)	3	4.6	Bioethical
bioethical protection (5)	3	4.6	bioethical
discursive protection (8)	8	12.3	bioethical
scandals in trials (3.5)	3	4.6	bioethical
technical committees (13)	6	9.2	technical
healing trials (16)	3	4.6	healing
communitarian committees (7)	10	15.4	communitarian
communitarian protection (5)	3	4.6	communitarian
concrete protocols (9)	2	3.1	communitarian
global inequalities (4)	1	1.5	communitarian
poor subjects (10)	4	6.2	communitarian
protecting bodies (8)	3	4.6	communitarian
uncertain research (6)	3	4.6	communitarian
TOTAL	65	100.0	

This discourse graphic is presented on page 278.

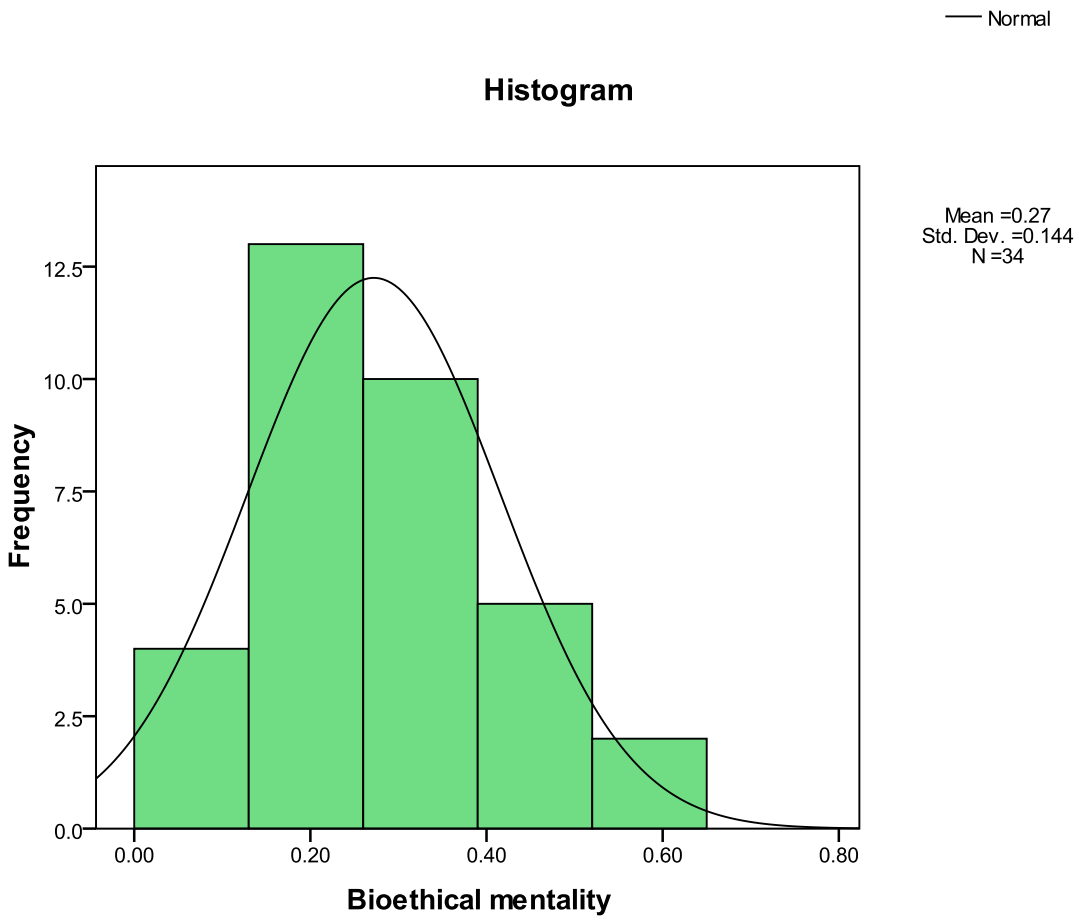
Appendix 4:
Histograms

In order to justify the types of statistical analyses I performed, I am presenting the histograms of my quantitative data. Each mentality is presented in a separate graphic.

PRAGMATIC MENTALITY



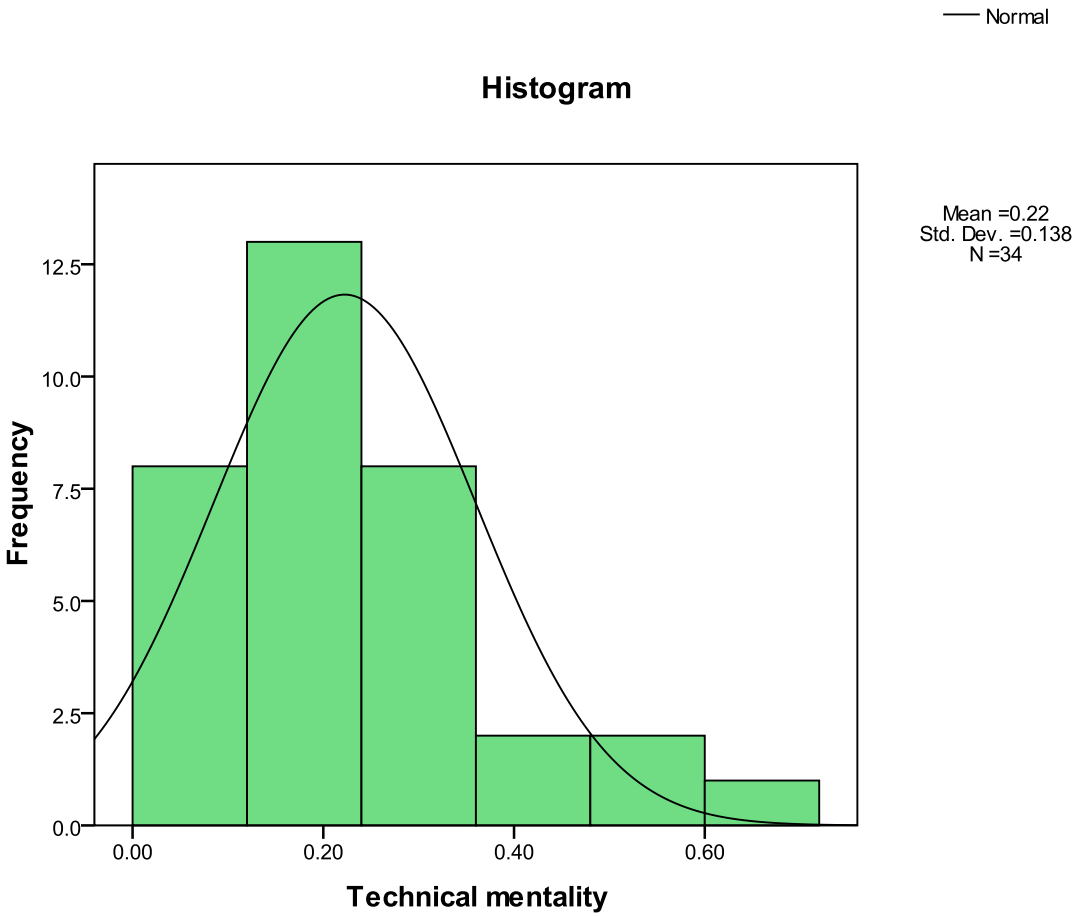
Type of analysis: non-parametric tests



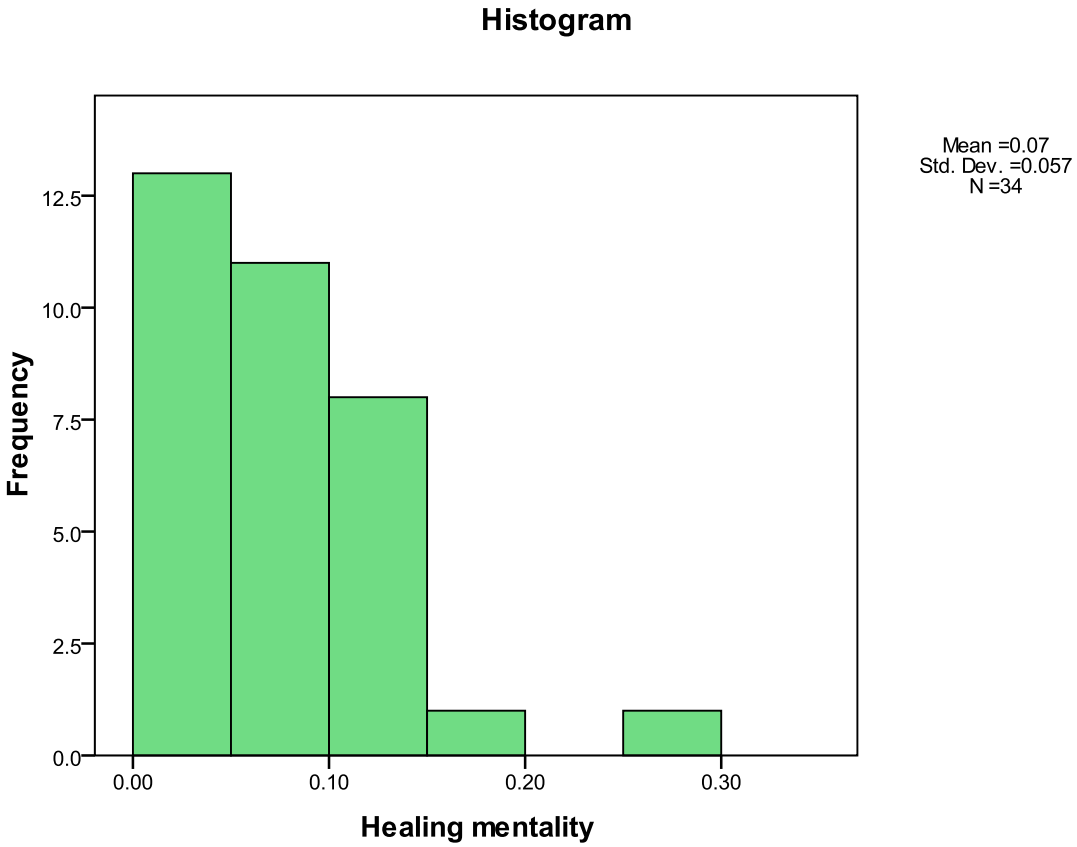
Type of analysis: parametric tests.

The normal curve has been added to this graphic in order to show that these data can be considered as normally distributed. Thus, whenever the bioethical mentality was assessed in isolation, parametric tests were performed. However, non-parametric tests were used when this mentality was compared to other mentalities.

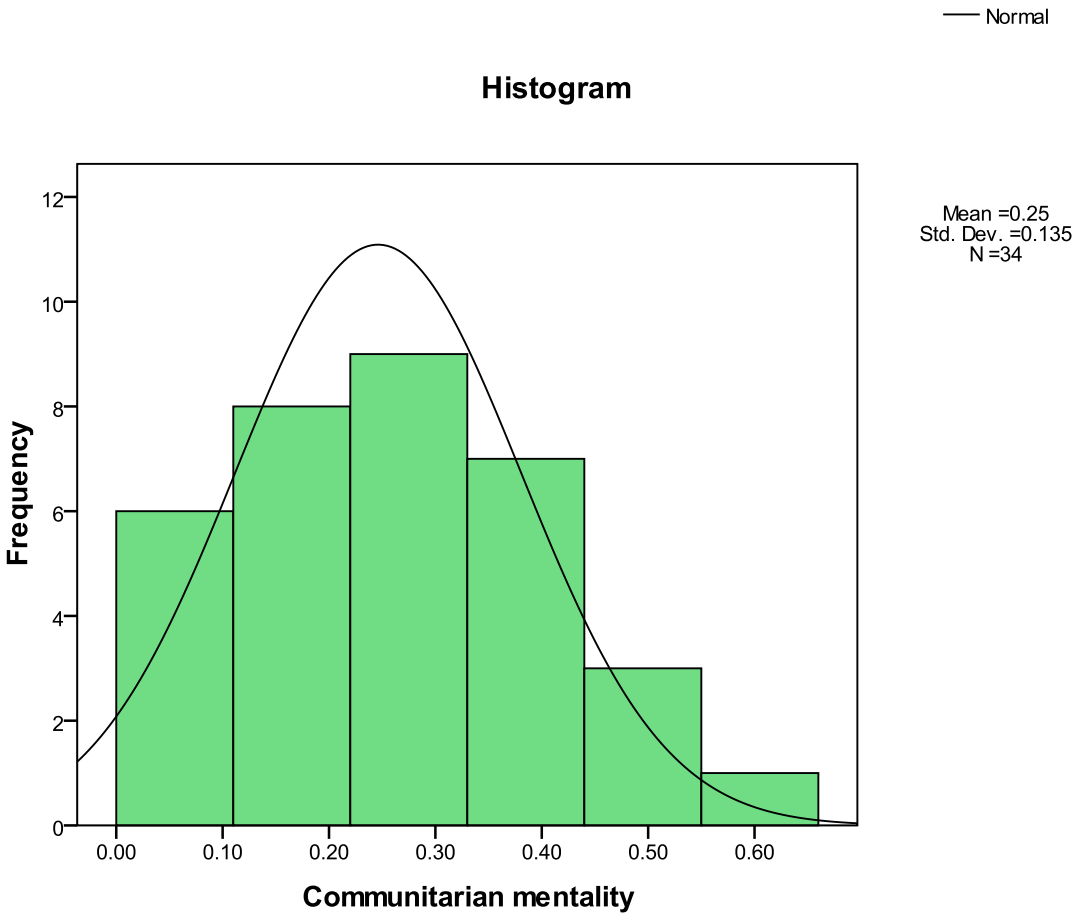
TECHNICAL MENTALITY



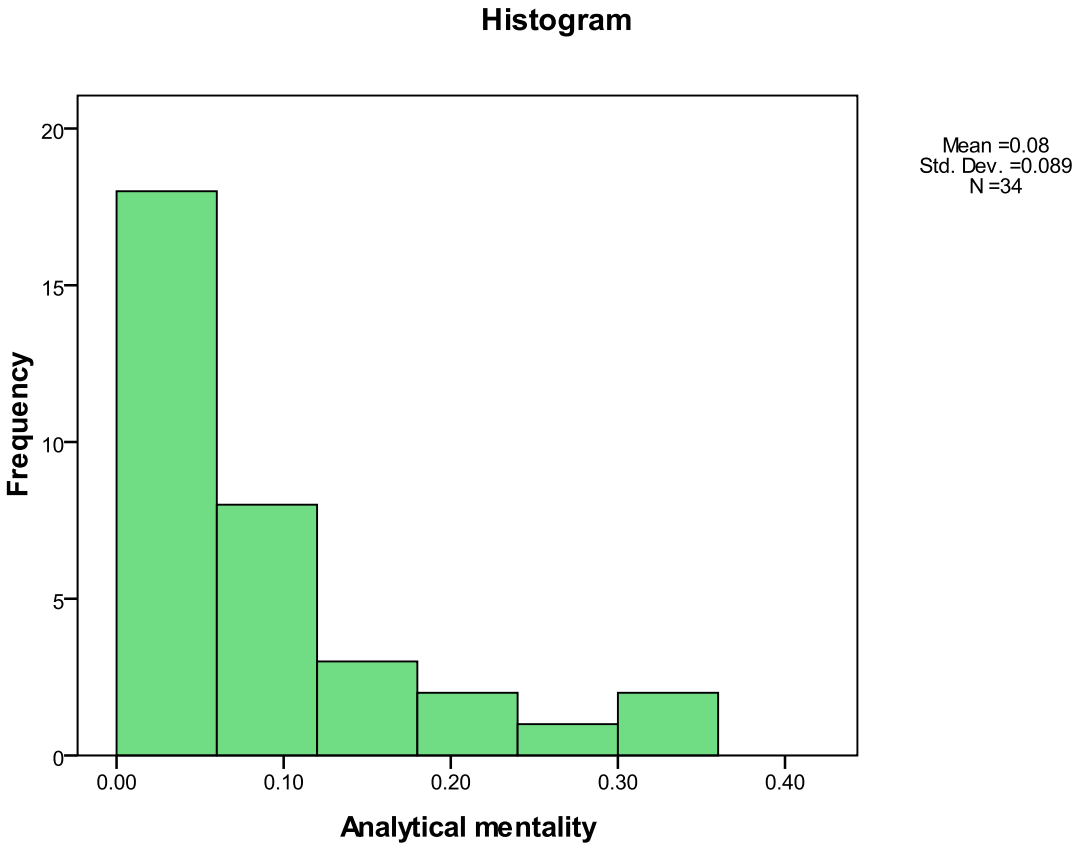
Type of analysis: parametric tests



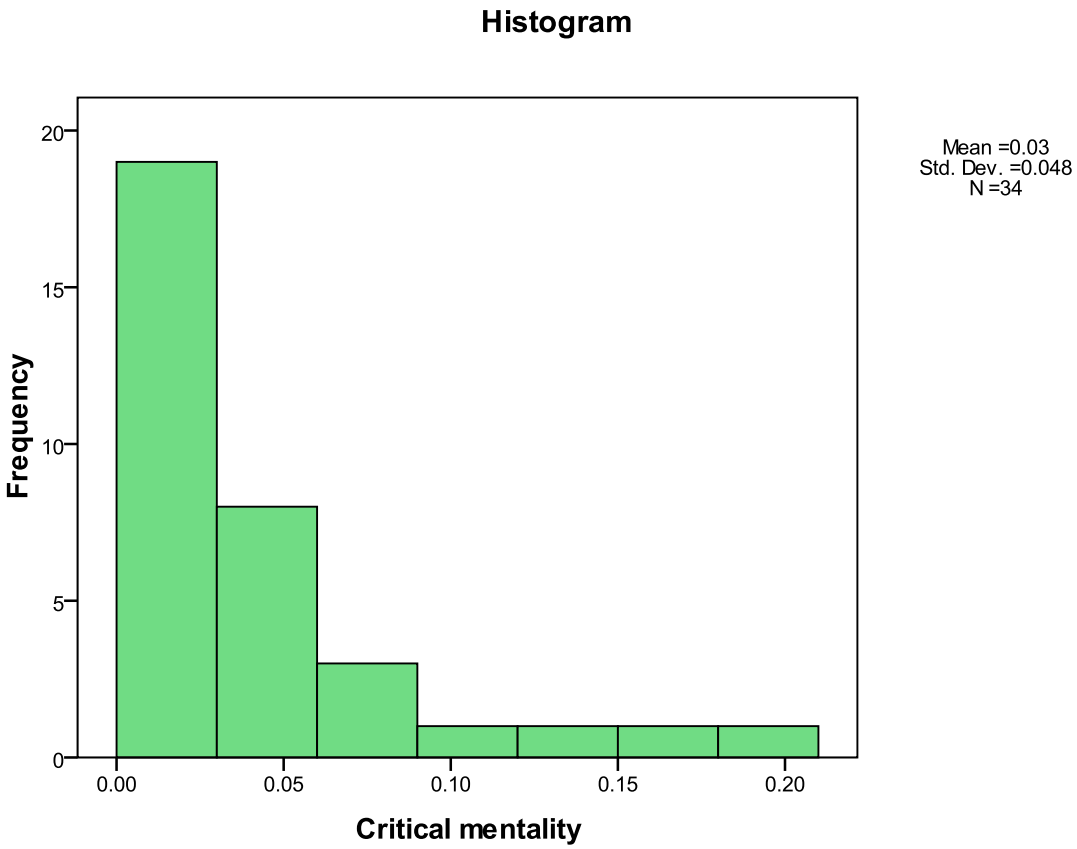
Type of analysis: non-parametric tests



Type of analysis: parametric tests



Type of analysis: non-parametric tests



Type of analysis: non-parametric tests

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